Nos. 16-2302, 16-2615

United States Court of Appeals for the Federal Circuit

GILEAD SCIENCES, INC.,
Plaintiff-Cross-Appellant,

v.

MERCK & CO., INC., MERCK SHARP & DOHME CORP., AND ISIS PHARMACEUTICALS, INC.,
Defendants-Appellants.

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA IN CASE NO. 5:13-CV-04057-BLF

GILEAD'S PRINCIPAL AND RESPONSE BRIEF

Juanita R. Brooks
Jonathan E. Singer
Craig E. Countryman
Fish & Richardson P.C.
12390 El Camino Real
San Diego, CA 92130
(858) 678-5070
brooks@fr.com; singer@fr.com;
countryman@fr.com

Deanna J. Reichel
Fish & Richardson P.C.
3200 RBC Plaza
60 South Sixth Street
Minneapolis, MN 55402
(612) 335-5070
reichel@fr.com

Elizabeth M. Flanagan
Robert M. Oakes
Fish & Richardson P.C.
222 Delaware Avenue
17th Floor, P.O. Box 1114
Wilmington, DE 19801
(302) 652-5070
flanagan@fr.com; oakes@fr.com

E. Joshua Rosenkranz
Rachel Wainer Apter
Edmund Hirschfeld
Orrick, Herrington & Sutcliffe LLP
51 West 52nd Street
New York, NY 10019-6142
(212) 506-5000
jrosenkranz@orrick.com

CERTIFICATE OF INTEREST

Counsel for Plaintiff-Cross-Appellant certifies the following:

1. The full name of every party represented by me is: Gilead Sciences, Inc.

2. The name of the real party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is: N/A.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are: N/A.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or agency or are expected to appear in this court are:

Fish & Richardson P.C.: Juanita R. Brooks, Jonathan E. Singer, Douglas E. McCann, Craig E. Countryman, Deanna J. Reichel, Elizabeth M. Flanagan, Robert M. Oakes, John M. Farrell, Gregory R. Booker, and Joseph B. Warden.

Orrick, Herrington & Sutcliffe LLP: E. Joshua Rosenkranz, Rachel Wainer Apter, Edmund Hirschfeld.

Dated: March 20, 2017

/s/ Jonathan E. Singer
Jonathan E. Singer

TABLE OF CONTENTS

Page

TABLE OF CONTENTS (continued)

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

STATEMENT OF RELATED CASES

There has been no prior appeal to the Federal Circuit or any other appellate court in this case. There is no case known to counsel to be pending in this or any other court that will directly affect or be directly affected by this Court's decision in the pending appeal.

STATEMENT OF JURISDICTION

This is an appeal from an August 16, 2016 final judgment holding U.S. Patents 7,105,499 and 8,481,712 unenforceable in this lawsuit against Gilead based on the doctrine of unclean hands but denying as moot the pending JMOL motions that those patents' asserted claims are invalid. Appx1-66. Merck and Isis filed their Notice of Appeal on unclean hands on August 23, 2016. Appx34049-34052. Gilead filed its Notice of Cross-Appeal on invalidity on September 2, 2016. Appx34053-34056. Each Notice was filed within the 30-day time limit set by Federal Rule of Civil Procedure 4(a)(1)(A). This Court thus has jurisdiction over the appeal and cross-appeal under 28 U.S.C. § 1295(a)(1).

INTRODUCTION

This case arises out of Merck's effort to profit off a remarkable cure for the Hepatitis C virus (HCV) that it did not discover: Gilead's sofosbuvir. But this appeal is really about Merck's egregious misconduct in lying to steal the secret discovery of Gilead's predecessor, Pharmasset; improperly patenting that discovery as its own; and then suborning perjury, both before and during trial, to cover its tracks and bolster its validity case. Specifically, this appeal is about the steps the district court had to take to prevent Merck from reaping the rewards of its misconduct.

Afflicting over 170 million people, HCV causes liver damage and can lead to liver failure and death. For years, the "best" treatment was a harrowing long-term regimen of injections with severe side effects, which only worked half the time and could not be taken by many patients.

Many companies raced to discover a better cure for all by finding a compound that would inhibit a key enzyme essential for HCV replication, NS5B polymerase. Only Pharmasset succeeded. It invented a unique compound, PSI-6130, which was active against HCV and safe for humans. After years of further work, it developed an even better compound, sofosbuvir, which cured HCV. Gilead—a leading developer of antiviral medications, including preferred HIV drugs—acquired Pharmasset and guided several sofosbuvir-based products through clinical studies and into the hands of patients. The results were astounding. The once-daily pill Harvoni®, for example,

eradicates HCV in 95% of patients after eight or twelve weeks, without the debilitating side effects of prior drugs.

Merck was in the race to find an NS5B polymerase inhibitor, too, but it lost to Pharmasset after its leading drug candidate turned out to be toxic. Merck has now asserted that Gilead's cure infringes Merck's patents.

The problem, as the district court documented, is that Merck lied to obtain and protect those patents. In 2004, Merck dispatched its patent prosecutor, Dr. Philippe Durette, a lawyer and Ph.D chemist, to learn PSI-6130's confidential structure from Pharmasset, knowing it overlapped with his prosecution docket. Merck lied to Pharmasset about who he was, and those lies induced Pharmasset to disclose PSI-6130's structure to him. Then, even though contracts prohibited Merck from using Pharmasset's confidential information to its own competitive advantage, Merck did just that: Durette amended Merck's pending patent claims in 2005 to target Pharmasset's discovery.

When this litigation was about to expose the scheme, Merck tried to cover it up. Merck presented Durette as its corporate witness to testify about his 2005 claim amendment and prepared him for days before his deposition. Merck's lawyers then watched as Durette falsely, and emphatically, denied ever learning PSI-6130's confidential structure, despite documents showing he had. Even after learning that a Pharmasset witness could irrefutably show Durette learned PSI-6130's confidential structure, Merck did not confess or take corrective action. Instead, Merck doubled-

down on the deceit, bringing Durette to trial with a new (and contradictory) story to bolster its validity position that it actually possessed PSI-6130 as of the asserted 2002 priority date. That story, too, was false. Yet, Merck built its case around it and vouched for Durette as an "honest" person.

The district court watched this unfold live. In a thorough 65-page opinion, it found Merck "directed, advised, guided, and covered up misconduct." Appx59. Having assessed Durette's demeanor, the court found him "not credible" and found Merck "sponsored" his "fabricated deposition testimony and his false trial testimony." Appx53. Overall, the district court documented a "pervasive pattern of misconduct by Merck," including "numerous unconscionable acts": "lying to Pharmasset, misusing Pharmasset's confidential information, breaching confidentiality and firewall agreements, and lying under oath at deposition and trial." Appx1; Appx44. As the district court correctly concluded, any one of those acts "would be sufficient" to show unclean hands—together, they "unmistakably constitute egregious misconduct" that justifies invoking unclean hands to wipe out Merck's ill-gotten jury verdict. Appx44.

These conclusions were all amply supported and well within the district court's wide discretion to make credibility determinations, find facts, and balance equities. On appeal, Merck attempts to rewrite both the factual record and the unclean hands doctrine. The first ploy goes nowhere, given the evidence and highly deferential standard of review. And the second—a novel materiality standard—flouts decades of Supreme Court precedent. This Court should affirm.

STATEMENT OF THE ISSUES

1. Did the district court act within its discretion in striking Merck's jury verdict for unclean hands where Merck took Pharmasset's confidential drug structure, wrongly used it to write patent claims, and sponsored perjury by its lawyer to cover up its misconduct?

2. Do Merck's amended claims, which target Pharmasset's invention, lack written description where Merck did not possess the claimed sub-genus at the time it applied for the patent, and the specification provides no blaze marks to the claimed sub-genus?

3. Are Merck's amended claims, which target Pharmasset's invention, not enabled where the patents provide no data or articulated reasoning establishing the claimed sub-genus is effective against HCV?

STATEMENT OF THE FACTS

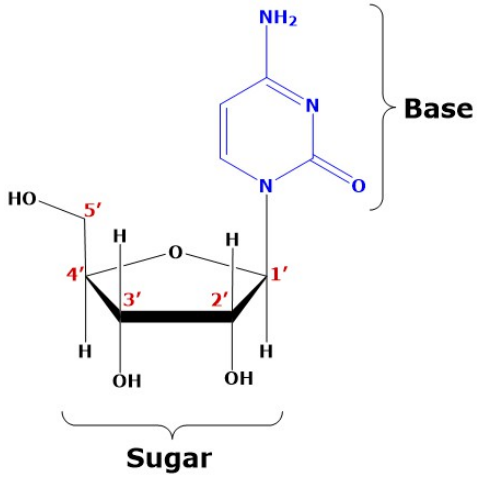
I. Gilead and Pharmasset Find An NS5B Inhibitor Cure For HCV, While Merck Fails.

Gilead's sofosbuvir is a sea change in HCV treatment—a safe, effective, and expedient cure. Until Gilead secured FDA approval in 2013, the leading treatment consisted of a grueling regimen of injections for 6-12 months. Appx19900-19901. The accompanying side effects were so debilitating that many were ineligible for the treatment and others refused it, even knowing the disease would eventually destroy their liver. *Id.* Worse yet, the therapy had a low cure rate—below 50%. *Id.*

Large pharmaceutical companies, like Merck and Roche, strove to do better. So did smaller biotechs, like Pharmasset and Idenix. Appx19911; Appx20049. One promising route was to block HCV from replicating. HCV replicates by making copies of its genetic code, or RNA. RNA is a long chain of links called "nucleosides."[1] The virus relies on enzymes, including NS5B polymerase, to copy the same RNA chain over and over. So scientists thought that one possible approach was to inhibit NS5B polymerase by using the enzyme to add a specially designed nucleoside that would stop the RNA chain by blocking the addition of the next link. That would cut the strand short—and grind viral replication to a halt. Appx19911-19913; Appx19901-19902.

[1] More accurately, the chain is made up of nucleo*tides*, which are nucleosides attached to a phosphate group. For simplicity, we refer to the nucleoside components of the chain.

That approach was challenging for several reasons. First, chemists can design endless varieties of nucleosides—literally billions. Appx20056. Each nucleoside has two connected parts—a sugar and a base:

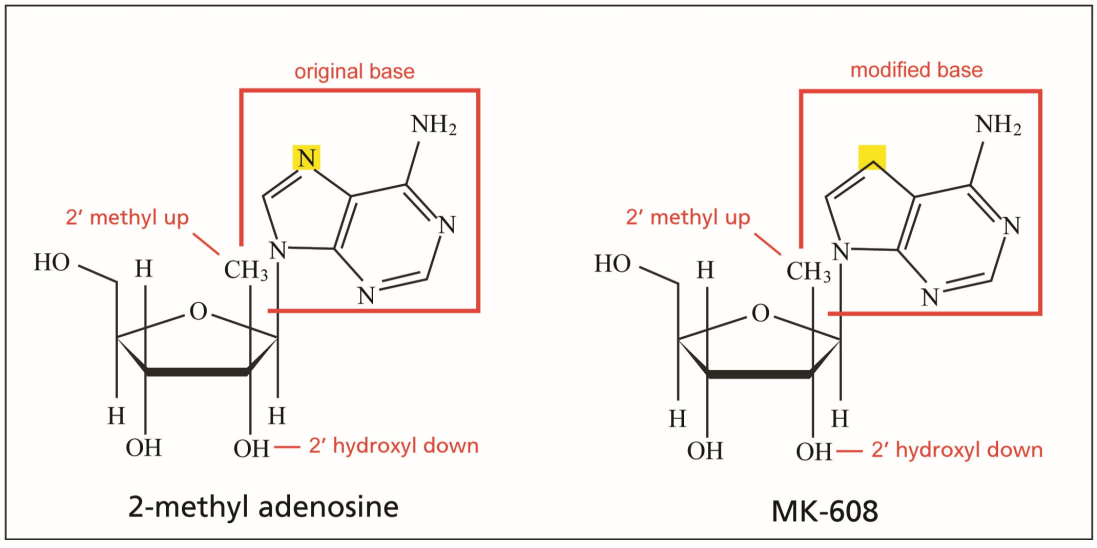


Each carbon on the sugar is represented by the intersection of bonds labeled sequentially from 1' (one prime) to 5' (five prime). Each of those carbons is bound to one group or "substituent" above the plane of the sugar (in the "up" position) and one below the plane (in the "down" position). Appx1247-1250. A chemist can pick from hundreds of possible substituents for each up and down position and millions of possible bases. Appx20129; Appx20147-20148. Second, there was no way to predict which among the billions of possible nucleosides would inhibit NS5B polymerase without testing them. Appx20055-20056. A one-atom change can be the difference between a promising compound and a dud, as illustrated at pp. 69-70. Third, human RNA needs to replicate too. Scientists therefore had to design a nucleoside that would stop the virus without killing healthy cells. Appx19912-19913; Appx20056.

Finally, you cannot evaluate a nucleoside's efficacy and toxicity without making it. Appx20056. And many nucleosides are very difficult to synthesize. Appx20041 (505:19-506:19) (Otto); Appx24825.

Given these constraints, scientists had to make hard choices about which nucleosides to pursue. Only after years of research was it evident that Merck chose wrong and Pharmasset, with Gilead, chose right.

Merck's Failure. Merck began its HCV efforts in 1998. It hired Isis to synthesize nucleosides that Merck would then test. Appx20291 (949:24-950:14) (Olsen); Appx19892 (166:19-22). Merck touts (at 4-5) the thousands of nucleosides that it tested, but it ultimately focused on two depicted below. Appx30370-30371; Appx30457; Appx20284 (922:11-923:16) (Olsen); Appx20298 (977:21-979:6) (Olsen). Both had double-ring bases and the same sugar with a methyl (CH_3) group at 2'-up and a hydroxyl (OH) group at 2'-down. This approach seemed promising because natural nucleosides, too, have a hydroxyl (OH) at 2'-down. Appx1253.



Appx30457; Appx20298 (977:21-979:6) (Olsen).

Merck first focused on 2'-methyl adenosine (on left). Preliminary results showed that its triphosphate inhibited NS5B polymerase. Appx30457; Appx20284-20285 (922:11-924:3) (Olsen). Merck and its expert described this as a "significant breakthrough, eureka moment," Appx20479, and a "game chang[er]," Appx20284—although Pharmasset and Idenix independently made the same discovery. Appx20038-20039 (494:15-499:3) (Otto); Appx24825-24826. But, by 2001, Merck realized the compound was toxic. Appx30457. So Merck modified the base (highlighted in yellow). The result was the compound on the right, MK-608—the only HCV nucleoside candidate Merck ever identified as promising enough to test in humans. Appx20303 (997:22-998:4) (Olsen).

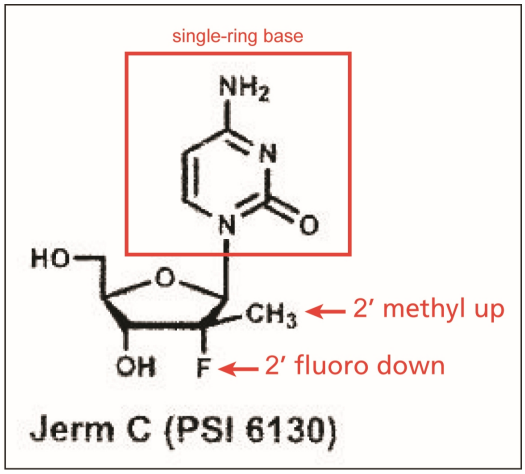
Upon learning that these two compounds inhibited NS5B polymerase, Merck filed for a patent. But it was not content to patent the nucleosides it actually made or tested. One of the inventors bluntly described Merck's patent strategy: "We want to block as many routes a[s] possible to effective HCV therapeutics." Appx22785. In keeping with this approach, in 2001, Merck filed broad provisional applications that eventually led to the patents-in-suit. Appx150-221; Appx223-298. As described more fully below (at 16-18), the patents' shared specification includes generic formulas that each encompass billions of compounds, almost all of which Merck never made, much less tested. Appx20202-20203 (777:19-781:1) (Secrist).

In 2006, Merck learned that its nucleoside research had failed. Testing MK-608

on just three patients proved it toxic. Appx20303 (997:22-998:4); Appx20335-20336 (1126:25-1128:11) (Olsen).

Pharmasset's Success. Meanwhile, Pharmasset defied convention and succeeded. In March 2001, Pharmasset independently made the same discovery that led to Merck's premature cry of "eureka"—it tested 2'-methyl adenosine and learned that it was active but toxic. Appx20038-20039 (494:15-499:3) (Otto); Appx29375; Appx29992.

This is where Pharmasset's path diverged from Merck's. Pharmasset believed that nucleosides with double-ring bases "are often associated with either overt toxicity or very subtle toxicity." Appx20039 (499:4-17) (Otto). So Pharmasset scientist Jeremy Clark created a nucleoside with a single-ring base. He then tried something counterintuitive and unnatural—placing a fluorine at the 2' down position. The result was PSI-6130:



Appx24826.

Mr. Clark's colleagues at Pharmasset were highly skeptical about his 2'-fluoro

down idea. They were convinced fluorine would make the compound toxic, and that he would be unable to synthesize it becasue "the chemistry was too difficult." Appx20041 (Otto). Defying expectations, Mr. Clark invented a way to synthesize it, and testing showed it was active against HCV and not toxic. Appx20041-20042.

That was a eureka moment. And it was Pharmasset's alone. Merck has never demonstrated that it was focused on this nucleoside or anything like it. The best it can point to (at 9-10) is a drawing by one chemist (Prakash) and a presentation by another (Song). Appx32431; Appx22824; Appx22879. Nothing ever came of Dr. Prakash's drawing. Merck never even tried to make, let alone test, that compound. Appx32286 (123:9-12; 124:6-9) (Bennet); Appx32311 (77:15-18); Appx32317 (178:4-9) (Song). And Dr. Song's presentation mentioned a *double-ring* base with a 2'-methyl up, 2'-fluoro down sugar—which falls outside Merck's claims. Appx22879. Dr. Song started to synthesize that compound, but never finished, and therefore Merck never tested it. Appx32316-32317.

Moreover, for reasons we explain below (at 44-46), Merck's suggestion (at 10-11) that Pharmasset got the idea for PSI-6130 from Merck's 2002 patent application and "intentionally infringed" Merck's patents is contrary to the district court's findings. Appx64.

Pharmasset applied for a patent on Mr. Clark's invention in May 2003. Appx20042 (511:15-512:2) (Otto). The Patent Office published it in January 2005 and later issued it as U.S. Patent 7,429,572. Appx29947-29987. Meanwhile,

Pharmasset focused on developing the compound into a cure: first, by spending years converting the structure into an effective drug that could be delivered to the liver, and second, by finding a partner with the resources to complete the expensive clinical trials necessary for FDA approval. Those efforts eventually led to sofosbuvir, a unique compound that links the sugar portion of PSI-6130 (2' methyl up, 2' fluoro down) to a different single-ring base (uracil instead of cytosine) and adds a "prodrug"—a chemical mask that ensures the compound reaches the liver without degradation. Appx19913-19917 (Sofia).

II. Merck Dupes Pharmasset Into Revealing PSI-6130's Structure.

Even before discovering PSI-6130, Pharmasset had been discussing a possible collaboration with Merck. With the exciting initial results of PSI-6130 in hand, Pharmasset revived that conversation in 2003. The discussions were subject to a pre-existing confidentiality agreement in which Merck promised not to use Pharmasset's confidential information except to evaluate a potential collaboration. Appx32151-32196 at ¶ 6; Appx30092.

Even so, Pharmasset was supremely cautious about disclosing PSI-6130's structure. As Merck's own witness admitted, structural information is a small pharmaceutical company's "crown jewels." Appx32410 (166:19-168:7) (MacCoss); Appx11. That was especially true for Pharmasset, a 12-person startup negotiating with a corporate behemoth. Appx20037 (490:13-15) (Otto).

So Pharmasset unveiled its confidential information about PSI-6130 in stages. It first shared highly promising data on PSI-6130 in September 2003. Appx32161-32181. At the time, it told Merck that PSI-6130 was a nucleoside that inhibited NS5B polymerase—the type of compound that Merck was also researching. Appx10. In October 2003, the parties signed an agreement permitting Merck to test PSI-6130 under the explicit condition that Merck would not try to discern the compound's structure. Appx30077-30083; Appx10-11. The agreement's title broadcast again that the compound was the "Pharmasset HCV NS5B Nucleoside Inhibitor." Appx30083. Merck's tests confirmed that PSI-6130 was "very encouraging." Appx32184; Appx11.

Merck next asked Pharmasset to provide limited information about PSI-6130's structure to "a Merck Medicinal Chemist, who is 'firewalled' from [Merck's] internal HCV program"—*i.e.*, a scientist who could not use the information to Merck's competitive advantage and was sworn not to disclose it to anyone else. Appx32184-32185; Appx11. So Pharmasset provided basic (though incomplete) structural information about PSI-6130 to Merck's Dr. Ashton, on February 4, 2004. Appx22918-22919; Appx22921-22922; Appx12. Dr. Ashton reported that PSI-6130 "represent[ed] a potentially good fit with Merck's existing anti-HCV portfolio." Appx22918.

Merck pressed for additional details on PSI-6130's structure. Pharmasset agreed to disclose the complete structure on a March 17, 2004 conference call, but

again only if Merck's participants were within the firewall. Appx31544 (RFS: "Firewall"); Appx19947 (382:8-12) (Durette); Appx15.

Merck then blatantly violated that condition: it put Dr. Philippe Durette, its in-house lawyer responsible for prosecuting its own patents on NS5B inhibitors, on the call. Appx14. At the beginning of the call, Pharmasset reiterated the importance of the firewall and asked the two Merck participants if they were firewalled from Merck's HCV program. Appx31544-31545. Both declared they were, Durette falsely so. Appx31545; *see also* Appx19960 (435:7-12) (Roemer). Reassured, Pharmasset disclosed its crown jewel: that PSI-6130 was a nucleoside with a 2'-methyl up, 2'-fluoro down sugar and a single-ring cytosine base. Appx31544-31545.

Merck never told Pharmasset that Durette was a lawyer, much less that he was prosecuting patents in Merck's directly competing HCV program. Appx19966 (Roemer). Instead, ***after*** Pharmasset made a "full disclosure of the compound structure," Durette acknowledged that there was "a problem" because it "seems quite related to things that I'm involved with." Appx31545. Durette nonetheless remained on the call and repeated that he was "within the firewall." *Id.* That was false and he knew it. *Id.*; Appx15-16.

As the district court correctly found, Durette's presence on the call was no "mistake." *See* Merck's Opening Brief ("OB") at 62; Appx14-16. Going into the call, there was no way for Durette or others at Merck to miss that PSI-6130 was a nucleoside HCV NS5B inhibitor, just like the subject of the patent applications

Durette was prosecuting. Appx12-14; Appx21632-21633 (2499:6-2501:4) (Demain); Appx23706; Appx32370, Appx20291-20292 (951:12-955:21) (Olsen). The technical details were not lost on Durette: He is a Ph.D. chemist who worked in Merck's laboratories for 25 years before becoming its patent attorney. Appx19954 (412:13-413:5).

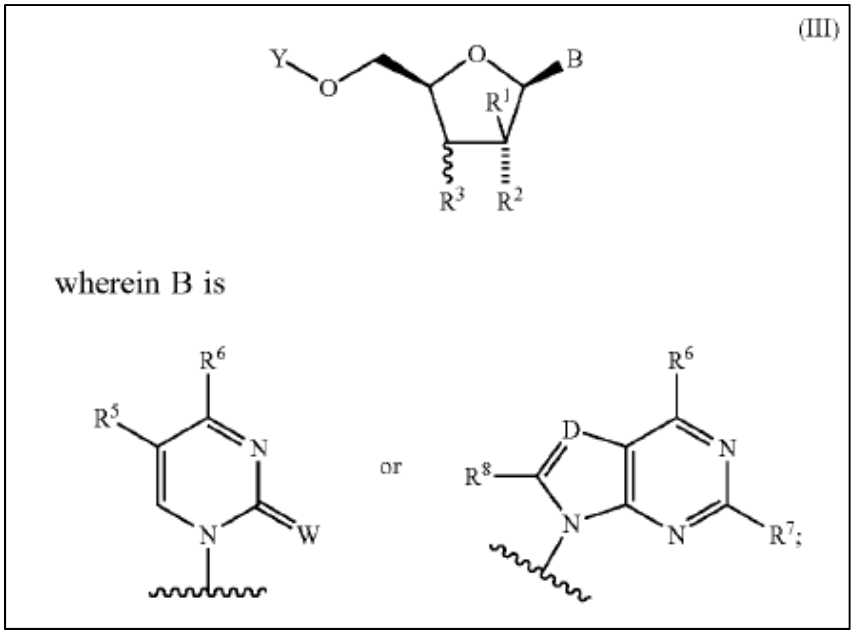
Merck's decision to place him on the call anyway was a flagrant violation of industry practice and of the written agreements with Pharmasset. Despite this, Merck never informed Pharmasset that Durette was prosecuting patent applications on its own NS5B inhibitors. Nor did Merck relieve Durette of those duties.

III. Durette Misuses Pharmasset's Firewalled Information To Narrow Merck's Pending Patent Application To Target PSI-6130.

Durette then used the firewalled information he took from Pharmasset and amended the claims of Merck's pending patent application to target PSI-6130. While Durette has offered contradictory explanations for the amendment, all that matters here is the district court's factual finding: "Durette would not have written new claims to cover PSI-6130 in February 2005 but for his improper participation on the March 17, 2004 patent due diligence call and learning the structure of PSI-6130 ahead of the structure being published." Appx18.

The Expansive Specification. Recall that when Durette initially filed his application, Merck was racing to find an HCV cure, and its patent strategy was to "block" as many competitors as possible. Appx22785. The specification common to

the '499 and '712 patents reflects that strategy, consisting of generic chemical formulas encompassing billions of potential compounds. Appx156-167; Appx20203 (Secrist). Take, for example, Formula III. Its basic structure includes a sugar component (top) with multiple variables (R^1, R^2, R^3, Y), attached to either of two base components (B) (bottom) each with multiple variables (R^5, R^6, R^7, R^8, D, W):



Appx158. There are numerous options for each variable: five categories of options for Y, three categories for R^1, eight categories for one of R^2 or R^3, and two categories for the other. *Id.* Bottom line, when a chemist does the math, Formula III covers a genus of "billions and billions of compounds"—orders of magnitude beyond what Merck ever synthesized and tested. Appx20203 (Secrist); Appx20296 (Olsen).

The specification does not label any option as "preferred." *See generally* Appx150-219. It provides no data on the activity of specific choices against HCV. Appx20055 (Seeger); Appx20203 (Secrist). The only possible source of guidance is

the specification's 149 examples (Appx171-217), which, if anything, point away from PSI-6130 or anything like it. *See* Appx20148-20149 (Secrist).

Durette Changes the Claims to Target PSI-6130. Before the March 2004 call, the '499 application's claims mirrored the specification. Claim 44, for example, copied Formula III's sugar component. *Compare* Appx27482-27483, *with* Appx158; Appx8-9.

Everything changed after Durette learned the structure of PSI-6130 in violation of the firewall. In February 2005, without prompting from the Patent Office, Durette canceled all pending claims and replaced them with two new and narrower claims. Appx19955-19956; Appx28318-28321. The result: claims that targeted Pharmasset's invention while excluding every example in the specification and every compound Merck had made or tested—including its lead compound at the time, MK-608. Appx19581-19582; Appx20053; Appx28320; Appx28328; Appx17.

Durette did not tell the patent examiner that he got the idea for this sub-genus from Pharmasset, that he learned from Pharmasset that a single-ring base, 2'-methyl up, 2'-fluoro down compound was "very active" against HCV, or that Merck had never made or tested any such compound by the time he filed his amendment (let alone by the 2002 priority date). Appx19955-19956. Claims 1 and 2 of the '499 patent issued in September 2006. Appx150; Appx220.

Durette didn't stop there. In February 2007, he filed the application that would eventually issue as the '712 patent. Appx28; Appx32258-32259 (Bergman). Merck used that application to further target Pharmasset's innovations, writing claims directed to metabolites of PSI-6130 and sofosbuvir. Appx32259-32260 (Bergman). Amended claims 9-11 of the '712 patent encompass a narrow subset of the specification's Formula III, while claims 1-3, 5, and 7 narrowed Formula I in ways the specification never suggested. Appx297-298; Appx20150-20151 (Secrist). Again, the changes excluded every example in the specification while targeting the single-ring base, 2'-methyl up, 2'-fluoro down structure of Pharmasset's inventions. *Compare* Appx297-298, *with* Appx158; Appx20203 (Secrist); Appx19581-19582.

IV. Merck Accuses Gilead Of Infringement, and Merck's Misconduct Surfaces.

When it became clear that sofosbuvir would receive FDA approval, Merck dug out its '499 and '712 patents-in-suit and demanded a 10% royalty from Gilead.[2] Appx300. But only Pharmasset's ingenuity and Gilead's development led to sofosbuvir. So Gilead brought this declaratory judgment suit challenging the validity of Merck's patents. Appx136-148.

[2] By that time, Roche and Idenix, two others who lost the race for an NS5B inhibitor, had also claimed rights to sofosbuvir. Merck has since acquired Idenix and has permitted Idenix to maintain several lawsuits against Gilead alleging that Idenix, not Merck, invented 2'-methyl up, 2'-fluoro down nucleosides as a treatment for HCV. *Storer v. Clark*, No. 15-1802 (Fed. Cir.); *Idenix Pharms., Inc. v. Gilead Sciences, Inc.*, Nos. 13-1987, 14-846 (D. Del.).

Given the mismatch between the patents' claims and the specification, Gilead sought to uncover why Merck had obtained claims directed to compounds like Pharmasset's rather than to its own compounds. That was when Gilead learned about the confidential information Durette obtained in violation of the 2004 firewall. Merck responded with a cover-up.

V. As Merck's Corporate Witness, Durette Lies at Deposition.

Merck began its cover-up by designating Durette as its Rule 30(b)(6) representative to testify about the '499 patent prosecution and why he amended the claims in 2005. Appx22036-22037 (181:25-182:16); Appx22331-22383. As the district court held, this testimony was central to Gilead's invalidity defenses, which alleged that Merck did not invent or possess the claimed sub-genuses in 2002. Appx52. After two full days of preparation with Merck's lawyers, Appx22017-22018, Durette unequivocally denied that he had ever learned the structure of PSI-6130 through confidential discussions with Pharmasset:

> Q. In March of 2004 were you involved in any discussion with Pharmasset whereby you were told what the structure was for their 6130 compound?
>
> A. ***No.***
>
> Q. You're sure of that?
>
> A. ***Yes.***
>
> Q. How are you so sure 11 years later that you were never told what the structure was for the 6130 compound?

> A. The structure was not revealed to me by individuals at Merck or otherwise. ***I'm positive*** of that. I ***never saw*** a structure of the Pharmasset compounds until it was published later on in time.

Appx32348-32349; *see also* Appx19938.[3]

Durette's testimony remained definitive even when confronted with a Merck email advising that he would attend the March 17, 2004 call: ***"I never participated in a due diligence meeting on March 17*** because the due diligence component of this particular deal was assigned to another attorney." Appx32348; Appx23706. He persisted after seeing a second email, written after the call, which requested destruction of any of his "notes from a March 17, 2004 telephone conference regarding PSI-6130 patent due diligence." Appx22034; Appx22290-22293 at Appx22291. He confirmed it was his "sworn testimony that ... during a telephone call on March 17, 2004, [he was] not made aware of the structure of 6130." Appx22034-22035 (168:13-169:18). Again, there was no equivocation:

> Q. How do you know that didn't happen? How do you remember that so well?
>
> A. Because I remember that I was not shown the structure of PSI-6130.
>
> ***
>
> Q. How do you remember it didn't happen 11 years later?
>
> A. Because I remember that … the structure was not disclosed to me.

[3] All emphasis is added unless otherwise indicated.

Q. How do you remember that so clearly?

A. Because I do.

Appx22035.

Durette also stressed that he would not have participated in such a call because "[i]t would have tainted my judgment as to what claims to pursue in the Merck/Isis collaboration." Appx32349.

Durette also denied that his decision to amend the '499 claims had anything to do with Pharmasset or PSI-6130. He testified that he had no memory of seeing the Clark application before amending the claims. Appx22022-22026. While he did not "recall precisely when I saw this publication," Appx22025-22026, he insisted it "would have had no impact, even if I had seen" it before filing the 2005 amendment, because the application disclosed "a large number of structures" and he did not recognize any as PSI-6130. Appx22032-22033. Merck asserts (at 30, 54-55) that at the time of this testimony, Durette was only looking at "six pages" of the Clark application, which did not disclose PSI-6130. Not true. As Merck's counsel conceded, Durette was shown the entire Clark application. Appx22022 (48:2-5), Appx22028 (54:6-20). And Gilead specifically directed Durette to "Paragraph 0168," which was a drawing of PSI-6130. Appx22026-22028. Even then, Durette remained adamant that although in 2015 he could see "the 6130 compound," he "didn't associate this structure" with PSI-6130 when the application published in 2005, because it was "within a large collection of compounds." Appx22026.

> Q. How is it that you know that you would not in January of 2005 have realized that Paragraph 0168, that chemical structure there, was 6130?
>
> A. Because this was ***one compound out of a plethora of compounds in the publication***.

Appx22027-22028.

Three weeks later, the truth came out. Merck deposed a Pharmasset representative, Alan Roemer, who testified about his contemporaneous notes from the call. Appx31544-31545. These notes showed that Durette learned PSI-6130's structure, asked numerous questions about it, and assured Pharmasset that he was within the firewall. *Id.*; Appx19958-19960. Thus, by no later than May 24, 2015, Merck's lawyers knew that Durette had lied at his deposition. Yet Merck never attempted to correct his testimony.

VI. Merck Elicits and Relies Upon False Trial Testimony from Durette.

Far from correcting the falsehood, Merck made it worse. Appx19933-19958. As documented more fully at p. 43, Merck sought to present Durette's testimony in support of its validity case, but to exclude evidence of his lies at deposition. The district court declined to allow that selective exclusion. Gilead thus came to trial prepared to demonstrate that Durette defrauded Pharmasset into disclosing the structure of its "crown jewels," lied to cover it up, and had admitted that his decision to amend the claims had nothing to do with anything he learned from the published Clark application. But Merck announced, for the first time in its opening, that it did not "dispute" what Durette had emphatically denied—that "Durette was on a phone

call with Pharmasset in which the structure of 6130 was described." Appx19895. Merck then introduced a new story: Durette's presence on the call was supposedly an honest mistake because he "didn't know that the compound that [Pharmasset was] going to disclose was within the scope of what [he was] working on." *Id.* Merck's counsel praised Durette as an honest person who "didn't try to cover up his mistake," but did "exactly what you want him to do" when he disclosed on the call that he might have a personal conflict. *Id.* As for Durette's deposition testimony, Merck asserted that Durette didn't lie but simply forgot he was on the call. *See id.*

Durette went even further on the stand, where the court found his testimony was "evasive" and "not credible." Appx27. He first testified he had simply forgotten that he was on the call, and had refreshed his recollection after reviewing certain documents. Appx19937 (344:1-7); Appx19948 (386:6-15). But the only documents he mentioned were the same ones he was shown at deposition, which did not refresh his recollection then. Appx32348; Appx23706; Appx22034; Appx22291. He next testified that his presence on the call was an honest mistake because he had no idea that PSI-6130 would be related to his patent prosecution. Appx19939 (350:15-351:9); Appx19942-19943 (364:11-368:14). The district court found this testimony "not credible" in light of the contemporaneous documents demonstrating that Merck, and Durette, knew PSI-6130 was a nucleoside NS5B inhibitor, just like Merck's HCV docket. Appx24; Appx21631-21633 (2498:24-2502:4); Appx23706-23707; Appx32369-32370.

Merck and Durette also invented a new, nonsensical explanation for why Durette had amended the '499 patent claims. Durette testified that he filed the 2005 amendment "to get an allowance on the subject matter that was most important to the [Merck/Isis] collaboration." Appx19952 (404:14-19). But the district court found this story "false," Appx27-28, because the 2005 amendment excluded every compound that Merck and Isis had ever tested, including Merck's own clinical candidate at the time, MK-608. *Id.*

Despite his contrary deposition testimony, Durette also testified that the publication of Pharmasset's Clark application was what "led me to reexamine my docket" and "then file the [2005] secondary amendment," Appx19949 (390:20-391:9); *see* Appx19943-19944 (369:5-370:14), and that he immediately recognized PSI-6130 in the Clark application because it was featured prominently, with examples and data, Appx19948-19949 (389:10-390:14).

Merck's counsel continued to vouch for Durette, arguing in closing that "he's an honest person," that his conduct was "what an honest person would do," and that his deposition testimony was "an honest mistake." Appx20676 (1723:2-1724:19).

VII. The District Court Invokes Unclean Hands.

The district court found there was nothing honest about any of this. After observing Merck's counsel and Durette during nine days of trial, and watching video of Durette's deposition, the district court issued an exhaustive 65-page opinion finding the '499 and '712 patents unenforceable for unclean hands. Appx1-65.

Although Merck prefers to ignore the district court's comprehensive opinion and focus instead (at 1, 28, 35, 56, 66-67) on brief remarks made during a hearing, the court actually found that:

> Merck's misconduct includes lying to Pharmasset, misusing Pharmasset's confidential information, breaching confidentiality and firewall agreements, and lying under oath at deposition and trial. Any one of these acts—lying, unethical business conduct, or litigation misconduct—would be sufficient to invoke the doctrine of unclean hands; but together, these acts unmistakably constitute egregious misconduct that equals or exceeds the misconduct previously found by other courts to constitute unclean hands.

Appx44. The court added that "Merck's acts are even more egregious because the main perpetuator of its misconduct was its attorney." *Id.*

With respect to Merck's business misconduct, the court rejected Merck's attempt to portray Durette's participation on the call as a mistake, finding instead that "Merck's employees were fully advised in advance that Pharmasset would disclose its closely guarded PSI-6130 compound," which was an NS5B inhibitor like Durette's patent-prosecution docket. Appx45. The district court further found that Durette "improperly used" what he learned on the call "to inform his conduct in amending the '499 Patent claims." Appx46. Moreover, each of Merck's "unconscionable acts" of business misconduct had an "'immediate and necessary relation to … the matter in litigation' because the patents that resulted from this series of unconscionable acts are now asserted against Gilead." *Id.*

With respect to Merck's litigation misconduct, the court found "reprehensible acts by Merck and Dr. Durette" including repeated "false testimony in this case."

Appx47. The court juxtaposed Durette's initial insistence that he was "positive" he never learned the structure of PSI-6130 and his "sanctimonious[]" claim that doing so would have tainted his judgment in prosecuting Merck's patents with his trial testimony after having been caught on the call. Appx47-49. The court chronicled his multiple other lies, including his shifting explanations about why he was on the call, why he amended the claims, and whether he saw the Clark application and the impact it had on his decision to amend. Appx49-51. The court rejected Merck's attempts to explain away the inconsistencies as innocent mistakes, citing Durette's "persistent pattern of falsifications." Appx51.

The court tied Durette's lies directly to Merck, noting that Merck had provided him with legal counsel, designated him as its Rule 30(b)(6) witness, and spent substantial time preparing him to testify, and, further, that his "untruthful testimony" was "directed at and supported Merck's validity arguments, and went to the heart of significant issues in this case." Appx51-52; Appx57-58. In sum, the court concluded that Durette, Merck's own lawyer, "intentionally fabricated testimony in this case" and "Merck supported that bad faith conduct." Appx61-62.

Like the business misconduct, the court found that Merck's litigation misconduct had an "immediate and necessary relation to ... the matter in litigation" because Durette's false testimony was directed to Merck's "key invalidity defenses" for both patents. Appx52. By making "Durette a centerpiece of its case… Merck's litigation misconduct infects the entire lawsuit, including the enforceability of the '712

Patent." *Id.* The court concluded that Merck's misconduct undermined the integrity of the entire proceeding:

> The legal system requires witnesses to supply complete and truthful testimony. If a witness fabricates testimony, justice is not served and when an attorney lies under oath, the Court cannot sanction such conduct. Dr. Durette, as Merck's former employee and 30(b)(6) witness, lied repeatedly at his deposition and at trial.

Appx53. The court added: "The Court cannot condone such conduct from any witness, let alone an attorney." *Id.*

The court concluded by balancing the equities and determining that they favored a finding of unclean hands. Appx64.

Having deemed the patents unenforceable, the court denied Gilead's JMOL motions on invalidity as moot. Appx66.

SUMMARY OF THE ARGUMENT

I.A. Under Supreme Court precedent, a district court may dismiss a patent infringement suit if a patentee commits egregious misconduct that has an "immediate and necessary relation" to the suit.

B. The district court's thorough 65-page opinion finding this standard satisfied was not an abuse of discretion. Durette's repeated lies, and both his and Merck's misconduct, place this case squarely within Supreme Court precedent finding unclean hands. Despite Merck's attempt to rewrite the factual record, the district court found that Durette repeatedly lied to it and to Gilead, and that Merck engaged in a "pervasive pattern of misconduct." Appx1; Appx63.

Nor did the district court abuse its discretion in finding the balance of equities favored Gilead or in fashioning a remedy reaching both the '499 and '712 patents. Merck repeatedly tied both patents together at trial and presented false testimony from Durette that related to its written description arguments for both. And Supreme Court precedent supports applying unclean hands to all patents in suit. The result is particularly just when it is a lawyer who has lied. The unclean hands judgment should be affirmed.

C. Merck spends much of its brief arguing (e.g., at 43) that misconduct must have "confer[red] an advantage on the claimant or injure[d] its opponent" in order to constitute unclean hands. But Merck cannot add its own requirements to the Supreme Court's "immediate and necessary relation" standard, and this Court has

already rejected Merck's proposed standard. Moreover, any heightened materiality requirement is satisfied in this case, where Merck both attempted to benefit, and actually did benefit, from its pervasive business and litigation misconduct until the district court ended the charade.

II. Gilead conditionally cross appeals on written description and enablement. Many of the facts that support the district court's unclean hands determination—that Merck's claims were prompted by Gilead's work, not Merck's—also support JMOL for Gilead. The specification has no examples, data, or any other blaze marks for the claimed subgenus. The claims thus lack written description as a matter of law.

III. Merck also has no substantial evidence of practical utility, relying entirely on an unsupported assertion in the specification that skilled artisans would not have accepted as true without data. Nor does it have substantial evidence that the full scope of the claims could be practiced without undue experimentation. The claims lack enablement as a matter of law.

ARGUMENT

I. The District Court Acted Well Within Its Discretion In Finding Merck's Patents Unenforceable For Unclean Hands.

The district court catalogued a "pervasive pattern of misconduct by Merck," consisting of "systematic and outrageous deception," and a "series of unconscionable acts." Appx1, Appx44-46, Appx53, Appx56, Appx63. It described Merck's misconduct as "egregious," "unacceptable," "reprehensible," "serious" "outrageous," "unethical," "disturbing," and "persistent." Appx46, Appx54, Appx56, Appx58, Appx63-65. It found that Durette and Merck "lied repeatedly," engaged in a "persistent pattern of falsifications," presented "false testimony," were "untruthful," "dishonest," "duplicitious," and "sanctimonious," and "intend[ed] to deceive Gilead and the Court." Appx47-53, Appx55, Appx58, Appx63, Appx65. This conduct is particularly egregious given that Durette is an attorney and Merck's lawyers actively sponsored his false testimony. Appx44; Appx53.

This Court reviews all these factual findings with great deference, only for clear error. And it reviews the district court's ultimate decision to invoke unclean hands only for abuse of discretion. *Seller Agency Council, Inc. v. Kennedy Center for Real Estate Educ., Inc.*, 621 F.3d 981, 986 (9th Cir. 2010). Moreover, "[t]his court may not reassess, and indeed is incapable of reassessing, witness credibility and motive issues on review." *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1361 (Fed. Cir. 2001).

These standards of review doom Merck's efforts to relitigate the facts and persuade this Court to reweigh the equities. The governing standard is the one the Supreme Court has announced: Unclean hands applies to a patentee who commits egregious misconduct with an "immediate and necessary relation to the suit." §I.A. The district court did not abuse its discretion in finding that standard met in this case or in holding that the equities favored dismissing Merck's counterclaims. §I.B. Beyond that, Merck's only argument revolves around abandoning the Supreme Court's "immediate and necessary relation" standard for a heightened materiality requirement that both the Supreme Court and this Court, sitting en banc, have rejected. §I.C. This Court should affirm.

A. Unclean Hands Bars a Patentee Who Commits Egregious Misconduct With An Immediate And Necessary Relation To The Suit.

The unclean hands doctrine shuts the courthouse door "to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief." *Precision Instr. Mfg. Co. v. Automative Maintenance Machinery Co.*, 324 U.S. 806, 814 (1945). Courts enjoy wide discretion "in refusing to aid the unclean litigant." *Id.* at 815. They may employ the unclean hands doctrine in response to "[a]ny willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct," and are "not bound by formula" in fashioning an appropriate remedy. *Id.*

The doctrine "assumes even wider and more significant proportions" in the patent context. *Id.* at 816. It protects not only "the interests of the adverse parties,"

but also the public's "paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct." *Id.* at 815-16; *see also Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 246 (1944).

Of course, the unclean hands doctrine is not "a freestanding judicial sanction." (OB39). Courts "do not close their doors because of plaintiff's misconduct, whatever its character, that has no relation to anything involved in the suit, but only for such violations of conscience as in some measure affect the equitable relations between the parties in respect of something brought before the court for adjudication." *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933). In other words, a party's "unconscionable act" must have an "immediate and necessary relation to the equity that he seeks in respect of the matter in litigation." *Id.*

Two Supreme Court cases—*Keystone* and *Precision Instrument*—illustrate how the unclean hands doctrine operates in the patent context to protect not only the defendant but the integrity of the patent and judicial systems.

In *Keystone*, after obtaining a patent, the patentee learned of a possible prior use of its invention. Fearing that the prior use would "cast doubt upon the validity of the patent," the patentee bribed the prior user to sign a false affidavit and suppress evidence of the prior use. 290 U.S. at 243. With the potential prior use suppressed, the patentee successfully sued a competitor, obtaining a decree that its patent was valid and infringed. *Id.*

The patentee then brought a second infringement suit against other companies, asserting the same patent and four others. The patentee attempted to invoke the first judgment as support for a preliminary injunction in the second suit. *Id.* at 242. That caused no harm because the trial court denied the injunction, "upon condition that defendants give bonds to pay the profits or damages that might be decreed against them." *Id.* Soon after, the bribery and suppressed evidence were exposed, and the defendant moved to dismiss the second lawsuit for unclean hands. *Id.* at 241, 243.

The Supreme Court held that the patentee was guilty of unclean hands. The Court emphasized that the patentee had sought an unfair advantage by citing its prior verdict—in which the prior-use had been suppressed—in support of a preliminary injunction in the second case. As the Court held, "whenever a party who … seeks to set the judicial machinery in motion and obtain some remedy, has violated conscience, or good faith, or other equitable principle, in his prior conduct, then the doors of the court will be shut against him." *Id.* at 245. The Court acknowledged, "the maxim requiring clean hands" applies "only where some unconscionable act of one coming for relief has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation." *Id.* But it held the patentee's misconduct could not "fairly be deemed to be unconnected" from the second suit. *Id.* at 246. Because "[the] plaintiff did not come with clean hands in respect of any cause of action," the Court affirmed the dismissal of infringement claims for all patents-in-suit. *Id.* at 247.

The same principles shaped *Precision Instrument*. The plaintiff was a wrench company called Automotive. One of its employees snuck secret information about a new wrench design to an outsider, Larson, and together they formed a new entity, Precision, to patent and sell the stolen wrench. 324 U.S. at 808-09. The Patent Office declared an interference between the Larson application and a prior application from Automotive. Larson attempted to establish priority by submitting a fraudulent affidavit containing "false dates as to the conception … and reduction to practice" of his purported invention. *Id.* at 809.

Automotive eventually discovered Larson's perjury. *Id.* at 810-11. Instead of exposing it to the Patent Office, Automotive settled with Larson privately, with Larson conceding priority and assigning his patent application to Automotive. *Id.* at 812-14. The Patent Office granted both patent applications to Automotive. *Id.* After Precision began manufacturing a new wrench, Automotive sued Precision and Larson for infringement and breach of the settlement agreement. *Id.* at 814.

The district court dismissed the complaint "for want of equity," and the Supreme Court affirmed. *Id.* at 808. "Instead of doing all within its power to reveal and expose" Larson's fraud, Automotive had "procured an outside settlement of the interference proceedings [and] acquired the Larson application itself." *Id.* at 816. In doing so, Automotive prioritized expediency over its "uncompromising duty to report" to the Patent Office "all facts concerning possible fraud or inequitableness

underlying the applications in issue." *Id.* at 818. Thus, Automotive acted "in disregard of the public interest." *Id.*

The Court dismissed the suit for unclean hands even though Automotive was the victim—not the perpetrator—of the original fraud. *See id.* at 819 (finding it irrelevant that Larson and Precision "may have been more reprehensible" in actually committing perjury). Automotive "knew of and suspected the perjury and failed to act so as to uproot it and destroy its effects." Instead, it "acted affirmatively to magnify and increase those effects." *Id.* Because Automotive's conduct did "not conform to minimum ethical standards" it could not "assert and enforce the[] perjury-tainted patents and contracts," even against the perjurer himself. *Id.* at 816.

A third case, often cited as part of a "trio," is also relevant. In *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, the patentee applied for a patent for a glass-pouring device. 322 U.S. 238, 240 (1944). When the application encountered opposition at the Patent Office, the patentee "determined to have published in a trade journal an article by an ostensibly disinterested expert," describing its device as "a remarkable advance." *Id.* at 240. After the fake article published, the Patent Office granted the patent. The patentee sued Hazel-Atlas for infringement, and the court cited the fake article, finding the patent valid and infringed. *Id.* at 241. The fraud was eventually exposed and Hazel-Atlas moved to have the original judgment set aside. *Id.* at 239, 243.

The court of appeals held that it had no power to set aside the judgment because judgments could not be "alter[ed] or set aside … after the expiration of the

term at which [they] were finally entered." *Id.* at 239, 244. Based on the "historic power of equity to set aside fraudulently begotten judgments," *id.* at 245, the Supreme Court disagreed. In so holding, the court remarked that had the fake article come to light "at the original infringement trial," the district court would have been "warranted in dismissing [the] case" under the rule set forth in *Keystone*. *Id.* at 250. It also stressed that "tampering with the administration of justice in the manner indisputably shown here involves far more than an injury to a single litigant. It is a wrong against the institutions set up to protect and safeguard the public, institutions in which fraud cannot complacently be tolerated consistently with the good order of society." *Id.* at 246 (internal cites omitted).

B. The District Court Did Not Abuse Its Discretion In Finding Merck Committed Egregious Misconduct That Had An "Immediate and Necessary" Relation To This Case.

Merck's business and litigation misconduct fits comfortably within the egregious misconduct in *Precision Instrument* and *Keystone*. *Precision Instrument* found unclean hands in a patentee's failure to expose (someone else's) dishonesty in procuring a patent and *Keystone* found it in a dishonest attempt to gain an unfair litigation advantage. Both brands of dishonesty are present here.

1. The District Court Did Not Clearly Err in Finding Merck Committed Egregious Misconduct.

a. ***Business misconduct.*** As the district court chronicled in exhaustive detail, Merck intentionally violated its firewall agreement with Pharmasset to get its hands on

Pharmasset's confidential information and then tailored its pending patent application to target PSI-6130. Appx10-18. For starters, the district court was correct in concluding that Durette's presence on the Pharmasset call was no mistake—it was an intentional violation of Merck's firewall agreement with Pharmasset. Appx44-47; *contra* OB62. As the district court painstaikingly detailed, Durette and others at Merck knew PSI-6130 was a nucleoside NS5B inhibitor, the subject of Durette's prosecution work, yet they intentionally included him on the 2004 call. *See* pp. 13-16.

Once on the call, Durette lied about being firewalled to induce Pharmasset to disclose PSI-6130's structure. *See* pp. 14-15. Ironically, Durette himself explained the seriousness of this breach when he insisted, repeatedly: "I would not have participated in a phone call wherein it was a potential for the revelation of the structure [of PSI-6130]," because learning about another company's nucleoside HCV NS5B inhibitor "would have tainted my judgment as to what claims to pursue in the Merck/Isis collaboration." Appx32349. As Durette further explained: "Having structural information is very important as to what the competition is doing in its research efforts. We had a policy in Merck … [that] if there were potential licensing opportunities" in a specific area, due diligence on those opportunities "would be assigned to … an attorney that was not prosecuting" any related patent docket. Appx22038-22039; *see* Appx14; Appx32348-32349.

Yet Merck never told Pharmasset about the firewall breach, never confessed that Durette was prosecuting Merck's own competing patent application, and never

removed Durette from that prosecution. Instead, Durette used the firewalled information to amend the '499 claims. Appx18. Merck also never disclosed to the Patent Office that Durette got the idea to narrow his claims by using Pharmasset's confidential information.

In *Precision Instrument*, the Court faulted the plaintiff for failing to inform the Patent Office of someone else's fraud. Here Merck failed to inform the Office of its own lawyer's misconduct in coopting Pharmasset's confidential structure and then using it to amend its '499 patent. 324 U.S. at 818-19; *Clements Indus., Inc. v. A. Meyers & Sons Corp.*, 712 F. Supp. 317, 318 (S.D.N.Y. 1989) (dismissing plaintiff's claim for unclean hands where it extracted confidential information to improperly obtain trade secrets). That constitutes unclean hands.

Merck's repeated assertions that Durette "did not use confidential information from the call" because he "took no substantive action on the '499 application until after Clark published" is simply wrong. OB53-54; *see id.* 2, 34-36, 50. The district court found that "Durette would not have written new claims to cover PSI-6130 in February 2005 but for his improper participation on the March 17, 2004 patent due diligence call and learning the structure of PSI-6130 ahead of the structure being published." Appx18. Merck does not argue that this factual finding was clearly erroneous, and it was not.

As earlier noted (at 22-23), Durette testifed at deposition that he did not recall seeing the Clark application before he amended the '499, and that even if he had seen

it, the Clark application "would have had no impact" on his amending the pending Merck claims because it disclosed "such a large number of structures" and he never associated any of those structures with PSI-6130. Appx22025-22028; Appx22032-22033. Merck now tries to reinterpret the Clark application's disclosure, but the district court did not clearly err by holding Merck to Durette's original story.

b. ***Litigation misconduct.*** Merck's subsequent cover-up was worse than the original offense, as cover-ups often are. When called upon to defend both patents in ligation, Merck realized that its claims would lack written description if the jury thought the patent did not have "blaze marks" to the narrower sub-genus, including PSI-6130. *See, e.g., Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1367-68 (Fed. Cir. 2011). Likewise, Merck knew the jury could use the fact that it tailored its claims only after fraudulently gaining access to Pharmasset's confidential information as evidence that Merck did not possess the claimed sub-genus in 2002. *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998). So Merck introduced a series of lies to bolster both patents. Appx52; Appx59-60. The district court did not clearly err in finding that Durette repeatedly and intentionally lied throughout this case—and that Merck sponsored those lies. Appx23-28; Appx47-53; Appx59. That alone supports the unclean hands finding.

Merck first tried to hide the connection between its claim amendments and its knowledge of PSI-6130's confidential structure by having Durette repeatedly and unequivocally insist at deposition that he never learned PSI-6130's structure. Durette

maintained this façade even after being confronted with documents showing he was on the call and had learned the structure. *See* pp. 20-22.

Durette's deposition testimony was not "ambiguous," OB21, 58-59, and the district court did not clearly err in finding as much. Appx23-28; Appx47-53. Having watched the video of Durette's deposition and observed his demeanor at trial, the district court was best positioned to identify Durette's repeated lies. And Durette's testimony is dominated by definitives—"I'm positive"; "I never saw." "You're sure of that? … Yes."—not hedging. *See* pp. 20-22. Merck has no basis for challenging this issue under any standard.

And after Durette's deposition, Merck did not correct the record. Instead, Merck prepared Durette to again lie, repeatedly, at trial. To take just one of several examples discussed above, Merck supported its written description case by eliciting testimony from Durette that he filed the 2005 amendment "to get an allowance on the subject matter that was most important to the [Merck/Isis] collaboration." Appx19952 (404:14-19). This was incredible, as the district court found. Appx27-28. Far from focusing on what was most important to the Merck/Isis collaboration, the 2005 amendment excluded every example in the patent and every compound that Merck and Isis had ever tested, including Merck's own lead compound, MK-608. *Id.*

It is no answer for Merck to say (at 47) that Durette eventually admitted at trial that he learned PSI-6130's structure on the March 2004 call. Durette confessed only after being caught red handed. What's worse, Durette never stopped lying about what

he knew before the call, why he amended the claims, and whether he saw the Clark application and the impact it had on his decision to amend. *See* pp. 20-25; Appx49-51.

The district court did not clearly err in attributing Durette's lies to Merck. Appx51-52; Appx58-59; *contra* OB2, 36, 46, 57. Durette was Merck's corporate witness on the reasons for amending the '499 patent. Merck's lawyers spent two days shaping his deposition testimony. They prepared him for trial, where they elicited lengthy (and false) testimony from him on written description. *See* pp. 23-25; Appx19949-19952. Merck vouched for Durette in closing, calling him "honest" three times. Appx20676. Judge Freeman, who observed the trial firsthand, did not clearly err in finding that Merck made "Durette a centerpiece of its case, from the opening statement to the closing argument," and used his testimony on "the key invalidity defenses presented to the jury." Appx52.

Merck says it "hid nothing" about Durette's participation on the 2004 call, and "[i]f anything, Gilead willfully blinded itself to Merck's position." OB48, 57-58. Merck cites a post-trial declaration, Appx22212-22213, which points back to a pre-trial interrogatory response, Appx22266-22267, which cites to the same documents that Durette was confronted with at his deposition. But Merck served that response ***before Durette's deposition***, so if it really were inconsistent with Durette's deposition testimony as Merck now asserts, then Merck had a responsibility to correct Durette's untruthful testimony right there on the spot. *See* ABA Model Rule 3.3(a)(3) ("If a lawyer, the lawyer's client, or a witness called by the lawyer, has offered material

evidence and the lawyer comes to know of its falsity, the lawyer shall take reasonable remedial measures, including, if necessary, disclosure to the tribunal."); Appx47. At a minimum, Merck should have done so before opening statements by submitting an errata under Rule 30(e), offereing Durette for another deposition, or telling Gilead before trial that Durette's testimony was false.

Similarly mystifying are Merck's attempts to score points by asserting that it "sought to exclude Durette's testimony as irrelevant and unduly prejudicial." OB2, 24, 32, 24, 26, 46, 48-49, 58, 68. Of course Merck wanted to exclude Durette's false deposition testimony. No party wants the jury to learn that it had a witness lie. Merck therefore moved *in limine* to exclude as "irrelevant" Durette's role in the March 17 conference call. Appx15723-15726. When that motion failed, Merck resisted Gilead's effort to call Durette to the stand. Merck stated that Durette would testify for Merck in support of its validity case, but that Gilead could not call Durette as an adverse witness in its case in chief because he was out of subpoena reach and no longer employed at Merck. Appx19404. When Gilead indicated its intent to play Durette's deposition at trial instead, and Merck realized how bad Durette's lies would look, Merck affirmatively offered Durette as a live witness and elicited new lies at trial. *See* pp. 23; Appx22219. All of that made the situation worse, not better.

***

In sum, the district court correctly found—and certainly did not clearly err in finding—that Merck committed egregious misconduct that had an ""immediate and

necessary relation to … the matter in litigation' because the patents that resulted from this series of unconscionable acts are now asserted against Gilead, Pharmasset's successor-in-interest." Appx46. The district court's findings, which revolve largely around on "witness credibility and motive," are well-supported and cannot be "reassess[ed]" now. *LNP*, 275 F.3d at 1361.

2. The District Court Did Not Abuse its Discretion in Finding the Balance of the Equities Favors Gilead.

Given its findings, the district court did not abuse its discretion in finding that the equities favored dismissing Merck's claims for unclean hands. Appx62-65.

On one side of the ledger, the court acknowledged that patent infringement is "serious," but noted that it is present in "virtually every patent case where unclean hands is asserted." Appx63. The court then addressed—and rejected—Merck's central point on the equities, that "Pharmasset knew that its PSI-6130 infringed Merck's patent applications." Appx64. The court found that Pharmasset "reviewed the '499 application in order to expressly stay clear of infringement." *Id.*

That was not clearly erroneous. First, contrary to Merck's repeated theme (OB10-11, 36, 64), Dr. Otto directed Pharmasset scientists to find "areas … that other people weren't working in." Appx20040. As "a very small company," there was no way Pharmasset could "directly compete" with a giant like Merck. *Id.* Thus, when Mr. Clark visited Dr. Otto in November 2002 to tell him about his idea for PSI-6130, he was holding a copy of a "patent application from Merck and a patent

application from … Idenix" in order to verify with Dr. Otto that his idea was not "in either one of those patents." Appx2040.

Pharmasset did not got the idea for PSI-6130 by "'cash[ing] [in]' on Merck's discoveries." OB36, OB10-11. Merck asserts (at 10, 64) that Pharmasset "had not made a single novel active compound by the time Merck's … applications published in July 2002." But what Merck's cited testimony actually says is that as of 2002, Pharmasset had not yet made any novel compound that was both active against HCV and not toxic, Appx20050-20051 (544:21-545:11), something Merck has still never done. Moreover, as explained above (at 16-18), Merck's 2002 application covered billions of compounds that Merck had never synthesized and tested. The application never suggested that the key was a compound like PSI-6130 with a single-ring base and a fluorine at 2' down. Thus, Dr. Otto reviewed both patents, "agreed with [Mr. Clark] that his idea was not in either one," and gave Mr. Clark the greenlight to proceed. Appx20040-20042.[4] Pharmasset's in-house counsel eventually demonstrated that it was possible, in hindsight, to find the individual elements of PSI-6130 in Merck's expansive application. OB12, 50, 64 (citing Appx20051). But Dr. Otto believed that Merck could not obtain valid patent claims to a single ring, 2'-methyl up, 2'-fluoro down compound because "there was no evidence that [Merck]

[4] Merck asserts that Pharmasset cited "one of Merck's 2002 patent applications as providing Pharmasset's 'rationale' for pursuing 2' methyl-up compounds." OB11. But the cited application was not the application at issue in this case, Appx19966.

had actually done any work" on any such compound, and "there was no data" and "no examples" suggesting Merck had ever "possessed" such a compound. Appx20042.

Second, in 2004 Merck did not tell Pharmasset that it "did not have 'freedom to operate'" because "Pharmasset was attempting to license a compound that Merck already had in their stable." OB14. Instead, Merck conceded that its patent applications "don't specifically disclose [PSI-6130]," and that PSI-6130 was "patentable." Appx32188. And although Merck suggested that "freedom to operate is a different issue" from patentability, Merck stated that it remained "interested" in collaborating on PSI-6130, which would have made no sense if PSI-6130 was already in Merck's "stable." Appx32188; OB14. Even later, in 2011, Merck considered purchasing Pharmasset for at least $7 billion to acquire sofosbuvir—a sum no rational company would pay for something it already owned. Appx32341-32342 (139:7-141:17); Appx22988-23047.

On the other side of the ledger, the court cited ample evidence in support of its conclusion that "Merck did intend to deceive Gilead and the court." Appx63. The court also found Merck inflicted "significant public harm regarding false testimony and improper business conduct that permeated this suit." Appx64. The court's interest in protecting the legitimacy of the patent and judicial system has weighed heavily in numerous precedents—notably *Precision Instrument* and *Hazel-Atlas*—and it was appropriate for the district court to consider it here.

This Court should reject Merck's attempts (at 63-65) to reargue these factual findings and discretionary weighing of the equities.

3. The District Court Did Not Abuse its Discretion in Applying Unclean Hands to the '712 Patent.

The district court did not abuse its discretion in holding that Merck's unclean hands infected the entire suit, including the '712 patent. Both the '499 and the '712 claim priority to the same provisional application that Durette filed in 2001. Appx25804. Durette filed the application that issued as the '712 patent and drafted its original claims. Appx24147-24153. Both the '499 and the '712 patents share a common specification, with the same formulas encompassing billions of compounds. Appx61. Both share the same 149 exemplary compounds, none of which falls within the claims. Appx20053. And both were part of a broader Merck campaign to patent Pharmasset's invention (single-ring base, 2'-methyl, fluoro nucleosides) rather than anything Merck made, tested, or exemplified in its patents, including its lead compound, MK-608.

Merck argued throughout trial that the two patents rose or fell together. Merck's closing treated them as one, interspersing the Patent Office's response to Durette's amendment of the '499 patent with the '712 patent. Appx20676-20678. Merck did not even separate its damages calculation instead asking for a 10% royalty for the pair. Appx21352-21353; Appx21360.

Most importantly, Merck relied on Durette's testimony as an authoritative Ph.D chemist and patent lawyer to defend written description for both patents. *See* Appx20678; Appx19949-19954 (391:10-404:13, 409:13-410:23). Thus, when Merck presented Durette's lies about the '499, it sought unfair advantages as to both patents-in-suit. Similarly, Merck's written description expert relied on testimony about the '499 patent's validity to defend the '712. Appx20643. The district court thus correctly concluded that Merck's "litigation misconduct infected this entire case, covering both patents-in-suit." *Id.* Merck is wrong to say (at 2) that the court invoked unclean hands for the '712 "without finding … litigation misconduct relating to that patent in any way."

Moreover, even if Merck's litigation misconduct had only been geared towards the '499 patent, a dismissal of all claims, including the '712 patent, would still have been proper. In *Keystone*, the Court dismissed all five patents, even though only one was related to the patentee's attempt to suppress evidence of the prior use, because the patents all covered different parts of the same device and had been asserted against the same infringing activity. *See* 290 U.S. at 246-47; *contra* OB70. Likewise, in *Precision Instrument*, Automotive asserted two of its own patents alongside the perjured one that Larson had assigned to it. *See* 324 U.S. at 807 n.1. Yet the Court dismissed all three patents because Automotive's failure to "uproot … and destroy" Larson's fraud, and its actions to magnify the fraud, had "impregnated [its] entire cause of action and justified dismissal by resort to the unclean hands doctrine." *Id.* at 819.

The district court found the same was true here. As in the Supreme Court's cases, "Merck and Dr. Durette's intentional litigation misconduct casts a darkness on this entire case that covers both patents-in-suit." Appx 60-61.[5]

The court was correct to refuse to abet inequity and protect the integrity of the proceedings before it. "The public welfare demands that the agencies of public justice be not so impotent that they must always be mute and helpless victims of deception and fraud." *Hazel-Atlas*, 322 U.S. at 246. Precisely because Merck litigated the two patents together—without any material distinction—a ruling that applies the unclean hands doctrine to only one allows Merck to escape without consequence. That would indeed render the court "impotent." The court properly refused to be party to a fraud, and its judgment should be affirmed.

C. Merck's Efforts To Supply A New Materiality Standard Fail.

Merck does not dispute that its misconduct had a "necessary and immediate" relation to this litigation—the only standard the Supreme Court has imposed. Rather, Merck spends most of its brief (at 39-56) arguing for a more stringent materiality

[5] Contrary to Merck's assertion (at 67-68), the district court did not hold the '712 patent unenforceable to punish Merck. The court commented that "it would be an odd result, to say the least, if Merck could engage in the substantial litigation misconduct exhibit in this case, yet face no penalty because the '712 Patent was deemed uncontaminated." Appx61. The court simply meant that, if the '712 patent were allowed to stand, the court would still be abetting a fraud, because Merck's lies had spilled into all parts of the case—which is exactly the standard the Supreme Court has applied.

standard that has been rejected by precedent and is satisfied by Merck's misconduct in any event.

1. This Court Has Rejected Merck's Materiality Standard as Incompatible with Supreme Court Precedent.

Merck cannot even settle on its preferred materiality standard. At times Merck urges (*e.g.* at 46) that misconduct is not "material" unless it altered the final decision regarding "the patent's validity" or "the litigation's outcome." That sounds like a "but-for materiality" standard, which both the Supreme Court and this Court have rejected as not necessary for a finding of unclean hands.

At other times, Merck tries (at 39-43) a different articulation: that the patentee must have actually benefited or the wrongdoer must have actually been injured by the misconduct in order for it to be material. But Merck never explains how this standard differs from but-for materiality—how can misconduct benefit the wrongdoer or injure its opponent if it did not impact the outcome of the proceeding? Moreover, the perpetrator's hands are equally unclean even if he has been caught—and therefore failed to gain advantage or inflict harm.

Keystone and *Precision Instrument* prove that the misconduct need not have ultimately altered the outcome of the proceeding, benefited the wrongdoer or harmed the victim. In *Keystone*, the patenttee's suppression of evidence of the prior used turned out to be unnecessary, because even taking the prior use into account, the district court still found the patent valid. 290 U.S. at 243. Second, the patentee's

wrongful attempt to use its prior verdict to support a preliminary injunction in the second case failed, because the district court denied the motion for a preliminary injunction. *Id.* Yet the Court found the attempt to gain unfair advantages sufficed for purposes of unclean hands—had the preliminary injunction been granted, "it is clear that [it] would have been a burdensome detriment to defendants." *Id.* at 246-47.

In so doing, the Court disagreed with the plaintiff's assertion—*contra* OB41—that unclean hands "does not apply unless the wrongful conduct is directly … material to the matter in litigation, and that where more than one cause is joined in a bill and plaintiff is shown to have come with unclean hands in respect to only one of them, the others will not be dismissed." 290 U.S. at 244-47. Instead, the Court held that unclean hands applies to any "violations of conscience [which] in some measure affect the equitable relations between the parties in respect of something brought before the court for adjudication." *Id.* at 245.

Similarly, in *Precision Instrument*, Automotive's "inequitable conduct" did not ultimately change the outcome of the proceeding, benefit Automotive, or hurt Larson or Precision. *Contra* OB42. Had Automotive exposed Larson's fraudulent use of its confidential information or his perjury to the Patent Office, the Office would have decided the interference in Automotive's favor, and Automotive would likely have been able to patent the misappropriated wrench idea. 324 U.S. at 808-10. By settling the interference privately, the same result seemingly obtained. *Id.* at 813. Yet the Court still applied the doctrine of unclean hands, without even considering whether

Automotive wrongfully gained an advantage or changed the outcome of any proceedings. Because Automotive attempted to assert and enforce "patent claims infected with fraud and perjury" its suit was dismissed for unclean hands, period. *Precision Instrument*, 324 U.S. at 819.

Therasense is in accord. *See* 649 F.3d at 1287. *Therasense* held that the inequitable conduct doctrine requires "but-for materiality," or proof that the Patent Office would not have issued a patent absent the patentee's wrongdoing. *Id.* at 1291. But the Court expressly declined to extend that requirement to unclean hands, recognizing that "this court's development of a materiality requirement for inequitable conduct does not (and cannot) supplant Supreme Court precedent" on unclean hands. *Id.* at 1287; *id.* at 1308 (O'Malley, J., concurring in part and dissenting in part) ("As in the *Keystone* and *Hazel–Atlas* cases, the Supreme Court in the *Precision Instrument* case did not look to whether the conduct in question would have rendered the plaintiff's application unpatentable.… There was no suggestion in the Court's opinion that the dismissal of the action would be appropriate only if, but for the conduct, the patent would not have issued."). *Therasense* explained why this is so: Inequitable conduct embraces a broader swath of conduct than unclean hands, including "the mere nondisclosure of information to the PTO." *Id.* at 1287. It also comes with a "more potent remedy—

unenforceability of the entire patent [against all] rather than mere dismissal of the instant suit [involving one party]." *Id.*[6]

None of Merck's non-patent cases (at 37-41) says otherwise. Most are distinguishable in other ways as well. For example, *Bein v. Heath*, 47 U.S. 228 (1848), did not say anything about helping "a person to reap the benefits of his own misconduct." Instead, it concluded that "one who asks for relief must have acted in good faith. The equitable powers of this court can never be exerted on behalf of one who has acted fraudulently, or who by deceit or any unfair means has gained an advantage." *Bein,* 47 U.S. at 247. And while *Kitchen v. Rayburn*, 86 U.S. 254 (1874), did say that a plaintiff cannot use the judiciary "to derive an advantage from their own wrong," it did not say that unclean hands can only be invoked where the plaintiff has already successfully derived such an advantage.

Merck's out-of-circuit non-patent cases (at 40-41) fare no better. Some are irrelevant, while others stand, at most, for the unremarkable proposition that unclean hands must relate to the suit and cannot be a freewheeling attack on an opponent's general morality. *See Dream Games v. PC Onsite*, 561 F.3d 983, 990 (9th Cir. 2009) (holding that the illegality of a computer gambling program did not bar its

[6] Merck is wrong to suggest (at 43-44) that *Therasense* simply acknowledged that the Supreme Court had not yet "articulate[d] a 'standard' for materiality" for unclean hands. *Therasense* plainly states that but-for materiality is not requied for unclean hands. To the extent *Regents of the Univ. of Cal. v. Eli Lilly Co.*, 119 F.3d 1559 (Fed. Cir. 1997), upon which *Merck* relies, suggested otherwise, it does not survive *Therasense*.

copyrightability, but observing that unclean hands "has been recognized when plaintiff misused the process of the courts by falsifying a court order or evidence"); *In re Uwimana*, 274 F.3d 806 (4th Cir. 2001) (finding former Rwandan ambassador could not avoid paying a debt to Rwanda by alleging a fear of persecution); *Stiegele v. J.M. Moore Imp.-Exp. Co.*, 312 F.2d 588, 594 (2d Cir. 1963) (refusing to adopt a general rule that unclean hands may be added to a case at any time, rather than under the standards of Rule 15); *Bailey v. TitleMax of Georgia, Inc.*, 776 F. 3d 797, 801-05 (11th Cir. 2015) (refusing to bar suit for unpaid overtime where the plaintiff had been underreporting his time, because he had done so at the defendant's instruction); *Performance Unlimited v. Questar Publishers, Inc.*, 52 F. 3d 1373, 1383-85 (6th Cir. 1995) (no unclean hands where the conduct involved ordinary commercial disputes over royalty payments, not fraud or perjury); *Mitchell Bros. Film Group v. Cinema Adult Theater*, 604 F. 2d 852, 861-65 (5th Cir. 1979) (theaters that displayed a copyrighted pornographic film could not invoke unclean hands by arguing the film was obscene); *Paramount Aviation Corp. v. Agusta*, 178 F. 3d 132, 147 n.12 (3d Cir. 1999) (rejecting conclusory unclean hands defense to contract dispute where there was no evidence of unconscionability or perjury); *Alcatel USA, Inc. v. DGI Technologies, Inc.*, 166 F. 3d 772, 796-97 (5th Cir. 1999) (affirming no unclean hands finding where the party had valid business justifications for its actions and there was no evidence of perjury); RESTATEMENT (SECOND) OF TORTS § 940 (1979) (unclean hands does not block the

polluter who seeks to prevent another's obstruction of a waterway, or the illegal gambling den operator who wants to sue for trespass).

Finally, this and other courts have recognized that presenting false testimony alone is sufficient to bar a suit, regardless of whether the plaintiff benefitted from the lies. *See, e.g., Aptix Corp. v. Quickturn Design Sys.*, 269 F. 3d 1369, 1374-75 (Fed. Cir. 2001); *Aris-Isotoner Gloves, Inc. v. Berkshire Fashions, Inc.*, 792 F. Supp. 969, 970 (S.D.N.Y. 1992) (finding fabricated testimony "unconscionable and thus warrants a finding of unclean hands"), *summarily aff'd*, 983 F.2d 1048 (2d Cir. 1992); *Mas v. Coca-Cola Co.*, 163 F.2d 505, 508 (4th Cir. 1947) (describing fabricating testimony and suborning the type of unconscionable conduct sufficient to bar relief). Indeed, courts always retain the inherent authority to dismiss a suit based on false testimony. *See, e.g., Wyle v. R.J. Reynolds Indus., Inc.*, 709 F.2d 585, 589 (9th Cir. 1983) ("[C]ourts have inherent power to dismiss an action when a party has willfully deceived the court and engaged in conduct utterly inconsistent with the orderly administration of justice.").

2. Any Heightened Materiality Requirement Is Satisfied Here.

Even if some sort of heightened materiality standard were required, any such standard would be satisfied here, because Merck not only attempted to unfairly benefit, but actually did benefit, both from its business misconduct and false testimony until the district court dismissed its patent infringement claims.

Merck repeatedly argues that all of Merck's business and litigation misconduct was "legally irrelevant" because if "Merck had already described, enabled and claimed

the infringing compounds in 2002, … it could not have stolen them from a meeting in 2004; and if Merck had not described and enabled the claims in 2002, the '499 patent was invalid anyway," regardless of what happened in 2004-2005 or at trial. OB2, 24, 34, 47. First, it is not dispositive that, in hindsight, Merck may not have needed to commit business misconduct. Despite Merck's constant refrain that "the '499 patent's claims already covered [PSI-6130] before the [2004] call" and Durette merely "narrowed the claims," OB2, 50, 52, at the time Durette amended the patent claims in 2005, he was not certain that the 41 exceedingly broad claims showed that Merck actually possessed PSI-6130 as of 2002. In other words, he did not know that eleven years later, a jury would wrongly find that Merck had adequately described, enabled and claimed PSI-6130 in its original 2002 application. That is why he amended the claims. Appx18; Appx26. In hindsight, the patentee in *Keystone* also could have enforced its patent without suppressing evidence of the purported prior use, but, its choice to suppress the evidence justified dismissal of the second suit. 290 U.S. at 243-46. The district court did not clearly err in reaching the same conclusion here.

Second, for all we know the unfair advantage before the Patent Office actually was necessary. The district court held that the '499 patent "resulted from [Durette's] series of unconscionable acts." Appx46. The court also found that "Durette would not have written new claims to cover PSI-6130 in February 2005 but for his improper participation on the March 17, 2004 patent due diligence call and learning the structure of PSI-6130 ahead of the structure being published." Appx18.

And Merck's original claims for billions of compounds would have been more vulnerable to multiple attacks at the PTO, as Durette himself acknowledged. Appx22347. Had Durette not misused Pharmasset's confidential information to narrow the claims of the '499 to specifically target PSI-6130, the Patent Office may have rejected the pending claims entirely. Unclean hands correctly resolves this type of uncertainty against the wrongdoer. *See, e.g., Hazel-Atlas*, 322 U.S. at 247 ("Doubtless it is wholly impossible accurately to appraise the influence that the [fake] article [the patentee cited in support of patent validity] exerted on the judges. But we do not think the circumstances call for such an attempted appraisal. … [T]hey urged the article upon the Circuit Court and prevailed. They are in no position now to dispute its effectiveness.").

As to the lies, Merck argues that it did not ultimately "benefit from," and Gilead was not ultimately "disadvantaged by" them. OB49; *see also* OB34-35, 46, 48 (once Merck's lies were exposed, the "only party conceivably injured" by testimony on the subject "was Merck"). Of course. A party generally does not benefit from false testimony when it gets caught. It only beneifts when it does not get caught. Unclean hands cases thus generally involve an unsuccessful ***attempt*** by the wrongdoer to secure a benefit or impose an injury through lying—that the district court discovers the lies and dismisses the suit for unclean hands shows that the patentee doesn't ultimately benefit in the end.

Here, had it not gotten caught, Merck would have obviously benefited from Durette's false deposition testimony. Durette's testimony that he never participated on the March 2004 call, never learned the confidential structure of PSI-6130, did not recall seeing the Clark application before filing his 2005 amendment, and would not have been able to discern PSI-6130 from the Clark application in any event, doomed Gilead's derivation defense. It was also critical to Gilead's written description defense, where courts have found that even a patentee's fair-and-square reliance on a competitor's public disclosure can support the conclusion that the patentee's amended claims lack adequate written description. *See Gentry Gallery*, 134 F.3d at 1479 (finding claims invalid for lack of written description where, among other things, patentee only amended his claim after he became aware of his competitor's work).

And Merck did actually benefit from Durette's false testimony, at least until the district court caught him: It secured a $200 million jury verdict rejecting Gilead's written description and enablement challenges and derivation defense. Before the jury, Merck elicited testimony from Durette that was extremely helpful to it on written description: (1) that the original claims "cover[ed] the Pharmasset compound … multiple years before the Clark publication"; (2) that Durette decided to amend the claims not to coopt Pharmasset's invention, but because he wanted to "expedite examination of the application" and because the 2'-methyl up, 2'-fluoro down compound "was a key invention of the Merck/Isis collaboration," Appx19944; and (3) that Merck had support for PSI-6130 all along and "could have filed that

narrowing application at any point in time because we already had" PSI-6130, *id.* Durette was the only witness who testified about the crucial 2005 amendment—the other inventors denied any knowledge or involvement in the prosecution. Appx17-18; Appx32266-32267 (100:11-17) (Bhat); Appx32269-32270 (55:24-56:6) (Eldrup); Appx32264 (255:11-15) (Cook); Appx32273 (129:1-10) (Carroll); Appx32279 (213:18-21) (Olsen). And the district court found that Durette lied when he told the jury that the amendment was not related to Pharmasset's confidential information. Appx26-28. As the district court concluded, "Durette's testimony played an influential role at trial on the critical issue of the relationship between the amended '499 claims drafted solely by Dr. Durette and the content of the earlier specification," and Merck elicited his "key" testimony that "the [amended] claims were fully described in the application he filed in 2002." Appx23; Appx53; Appx19952 (403:15-17).

That the district court eventually put a stop to the lies and ensured that they did not benefit Merck or harm Gilead does not mean that the district court abused its discretion. Quite the opposite. It means the district court correctly chose to guard the integrity of its proceedings. This Court should affirm.

CONDITIONAL CROSS-APPEAL

If this Court reverses the district court's ruling on unclean hands, it should vacate the jury verdict on the alternative ground that Merck's patents are invalid as a matter of law for lack of written description and enablement. These defects pick up where the unclean hands record leaves off: Given the district court's finding that the claims resulted not from Merck's work, but from its decision to misuse Pharmasset's confidential information, Appx45-47, it is no surprise that Merck's specification does not describe or enable the claims.

II. Merck's Patents Are Invalid As A Matter of Law For Lack of Written Description.

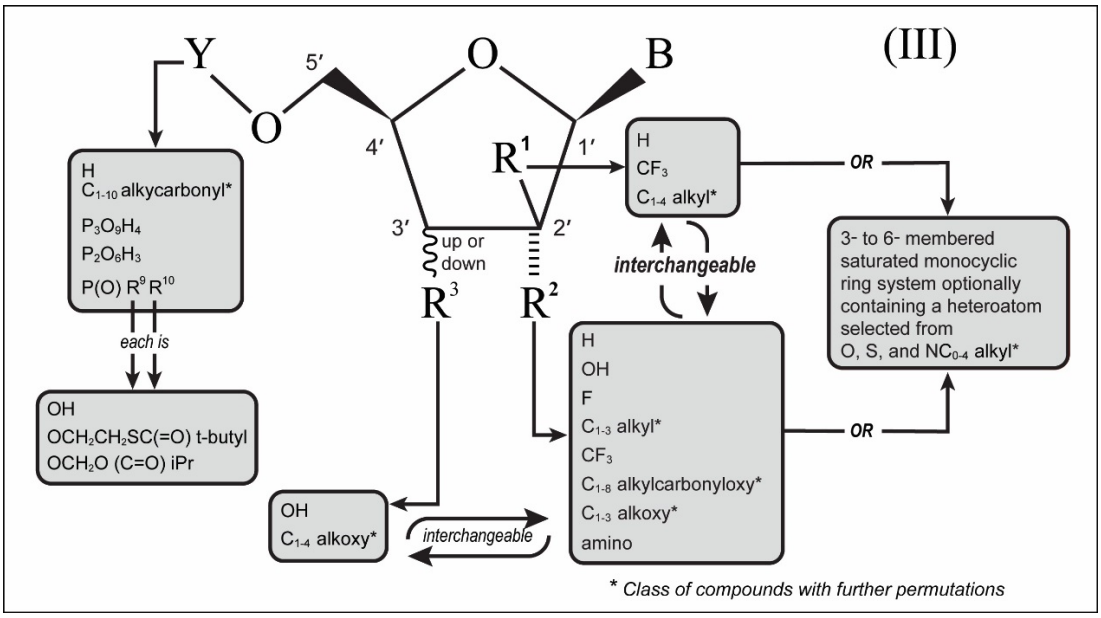
Merck's specification did not provide adequate written description for the challenged claims unless, on the initial filing date, it "clearly allow[ed] persons of ordinary skill in the art to recognize that [Merck] invented" the claimed compounds. *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1346 (Fed. Cir. 2013) (quotation marks omitted). A "mere wish or plan to obtain the claimed invention is not sufficient"—the specification must also show "possession" of the claimed compounds. *Id.* (quotation marks omitted); *see Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). Written description is a question of fact reviewed "for substantial evidence." *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1243 (Fed. Cir .2002).

The written description requirement plays a critical role in "cases involving priority"—particularly where, as here, a patentee initially discloses an enormous genus of chemical compounds and later amends the application to claim a narrower sub-genus. *See Ariad*, 598 F.3d at 1349. By using multivariable formulas—in which ranges of alternative substituents, or "Markush groups," may be placed at several bonding sites—a specification can easily define a genus containing billions of compounds. As this Court has made clear, such sweeping formulas alone do not demonstrate possession of later-claimed sub-genuses. *See, e.g.*, *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996). If they did, patentees could improperly use Markush groups to compile a list of hypothetical compounds and then claim priority when others actually invented them.

Specifically, this Court does not consider an amended sub-genus claim adequately described unless the specification expressly identifies the sub-genus or provides "blaze marks" that directed a person of skill to the claimed compounds. *Fujikawa*, 93 F.3d at 1571. "[S]omething more than the disclosure of a class of 1000, or 100, or even 48, compounds is required…. [O]ne cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326-27 (Fed. Cir. 2000). Rather, blaze marks must "indicat[e] or direct[] that [the] particular selection [in the claim] should be made rather than any of the many others which could also be made." *In re Ruschig*, 379 F.2d 990, 995 (C.C.P.A. 1967).

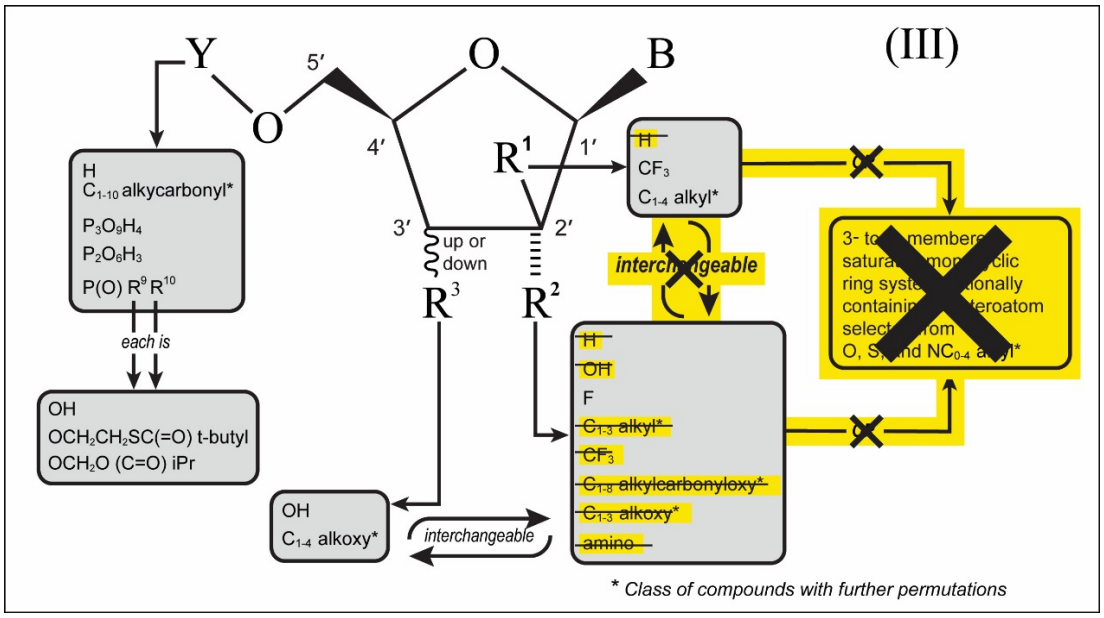
Thus, a later-filed claim to a particular sub-genus is ***not*** adequately described simply because each of its substituents was "literally" named as an option in the specification's broader multivariable formulas. *Novozymes*, 723 F.3d at 1349; *see Fujikawa*, 93 F.3d at 1571. The original patent specification must do more than "provide[] formal textual support for each individual limitation recited in the [amended] claims"—it must also direct a person of skill in the art toward the sub-genus as an "***integrated whole***." *Novozymes*, 723 F.3d at 1349.

Merck's amended claims are inadequate as a matter of law under that standard. As explained above (at 16-17), the specification recites sweepingly broad formulas encompassing billions of compounds. The challenged claims, in contrast, recite sub-genuses that are far narrower and specifically target Pharmasset's, not Merck's, innovations. Formula III, for example, provides that a Markush group of three alternative classes (including hydrogen) may be attached at 2'-up ***or*** 2'-down; and that a distinct Markush group of eight alternative classes (including fluoro) may also be attached at 2'-up (R^1) ***or*** 2'-down (R^2), as well as 3'-up or 3'-down (R^3). *See* Appx158; pp. at 16-17. Alternatively, the 2'-up and 2'-down positions may form a ring system. Appx158 (13:61-64). The following graphic annotates Formula III's sugar to show the possible substituents for each variable:



The final amended claims of the '499 and claims 9-11 of the '712 narrow those options dramatically. They eliminate the ring system option; restrict the first Markush group to 2'-up while omitting hydrogen as an option; and bar the second Markush group from 2'-up while omitting every option but fluoro. Appx20148-20151. In other words, the claims discard the vast majority of compounds within Formula III and define for the first time a sub-genus containing the single-ring base, 2'-methyl up, 2'-fluoro down structure of PSI-6130. *See* Appx220-221 ('499); Appx298 ('712). To help visualize this narrowing, the following graphic highlights and strikes out all the substituents that the final amended claims eliminated from Formula III's sugar:[7]

[7] Merck's opening brief obscures the extent to which the final amended claims narrowed the sugar, neglecting to mention that the Markush groups for R^1 and R^2 could originally be interchanged or replaced by a ring system. That is why Merck's excerpts of claims 6 and 44, both of which incorporated Formula III's sugar, end with a hanging "or"—they are incomplete. *See* OB8, 17.



Claims 1-3, 5, and 7 of the '712 effect a similar narrowing of Formula I. They also eliminate the ring system option and substantially constrict the possible substituents at several positions, including the base, 2'-up and 2'-down, in a way that targets the single-ring base, 2'-methyl up, 2'-fluoro down structure of sofosbuvir. *Compare* Appx227-228 (Formula I), *with* Appx297-298 (claims).

The specification failed to expressly identify any of those claimed sub-genuses, as Merck's expert acknowledged. *See, e.g.*, Appx20650 (1618:2-21) (Wuest). To satisfy the written description requirement, therefore, the specification had to disclose blaze marks sufficient to lead a skilled artisan to believe that the inventors possessed those particular sub-genuses, as distinct from "any of the many others which could also be made" from the specification's sweeping formulas. *Ruschig*, 379 F.2d at 995. There are no such blaze marks.

First, it is undisputed that the specification fails to disclose even *one* representative compound within the claimed sub-genuses. *See, e.g.*, Appx19582; Appx20638 (1572:3-6) (Wuest). Merck stipulated that "[n]one of the compounds described by structure in the 154 examples in the shared specification of the '499 and '712 patents are recited within the asserted claims." Appx19582. The absence of a single example within the scope of the claims significantly undercuts the adequacy of the written description. *See Novozymes*, 723 F.3d at 1348; *Boston Sci.*, 647 F.3d at 1364 ("[T]he lack of any disclosure of examples may be considered when determining whether the claimed invention is adequately described."); *cf. Centocor Ortho Biotech, Inc. v. Abbott Labs., Inc.*, 636 F.3d 1341, 1350-51 (Fed. Cir. 2001).

The specification is similarly devoid of any other blaze mark directing a skilled artisan toward the claimed sub-genuses. Just the opposite. Gilead's expert, Dr. Secrist, presented unrebutted testimony that the specification would have pointed "*clearly away*" from the claimed sub-genuses. Appx20149. *See Novozymes*, 723 F.3d at 1348 (finding no blaze marks to the claimed sub-genus where "the bulk of the specification focuses on using" a different parent enzyme). As he explained, the majority of the examples have a double-ring base and a hydrogen at 2'-up. Appx20149 (741:1-12). All the challenged claims exclude those possibilities. The vast majority of the examples also have no fluorine at any of the relevant positions (2'-down or 3'). Appx20149 (741:13-16). By contrast, the amended '499 claims and claims 9-11 of the '712 require, and the remaining claims of the '712 allow for, a

fluorine at one of those spots. Overall, therefore, Merck's 2002 application provided "no guidance at all to get from" the sweeping formulas in the specification to the eventually claimed sub-genuses. Appx20202-20205 (780:6-788:10); Appx20149-20152 (743:7-12, 750:11-755:21) (Secrist).

Merck offered no countervailing evidence of blaze marks. Instead, Dr. Wuest simply pointed out that each individual limitation of the claimed sub-genuses was ***separately*** listed as one of many alternatives in the specification's broad formulas, and appeared in some of the example compounds. In particular, Dr. Wuest noted that methyl appears at the 2'-up position in a minority of the examples; that fluorine sometimes appears at the 2'-down or 3' positions; and that a few of the examples feature single-ring bases. Appx20634-20635 (1556:5-1558:9). Even if true, these observations are beside the point. It is undisputed that no example contained all limitations of any sub-genus ***together***, as the claims require. Appx20634-20635 (1555:1-58:1); Appx20640-20641 (1580:1-84:20) (Wuest). And Dr. Wuest pointed to nothing that directed one of skill to combine the separately disclosed limitations in those particular ways. *Id.* Merck was obligated to do more than "provide[] formal textual support for each individual limitation recited in the [amended] claims"—it was also required (but failed) to direct a person of skill in the art toward the sub-genus as an "integrated whole." *Novozymes*, 723 F.3d at 1349.

This Court's *Novozymes* decision demonstrates the inadequacy of Dr. Wuest's testimony. The specification in that case also defined a broad chemical genus using a

multivariable formula. And, as here, later-filed claims recited a significantly narrowed sub-genus that made particular selections for several variables. 723 F.3d at 1341, 1348. The specification "literally described" those selections among many alternatives, *id.* at 1348-49—precisely what Dr. Wuest said about Merck's specification. Nonetheless, this Court held that the specification failed to demonstrate possession of the sub-genus as a whole, explaining that "[t]aking each claim—as we must—as an integrated whole rather than as a collection of independent limitations, one searches … in vain for the disclosure of even a single species that falls within the claims or for any 'blaze marks' that would lead an ordinarily skilled investigator toward such a species among a slew of competing possibilities." *Id.* at 1349. That is exactly the situation here.

In a tacit admission that *Novozymes* and related cases are fatal to its claims, Merck and its witnesses urged the jury to ignore controlling law and ask only whether "all the elements of the [sub-genus] claim can be found" individually in the specification's formulas. Appx20640 (1578:21-1579:23) (Wuest); *see also* Appx19952 (402:25-403:12) (Durette); Appx20670 (1699:7-9) (closing). That is simply not the law. Under this Court's precedent, any reasonable factfinder would have concluded that Merck's claims are invalid for lack of written description.

III. Merck's Claims Are Invalid As A Matter Of Law For Lack Of Enablement.

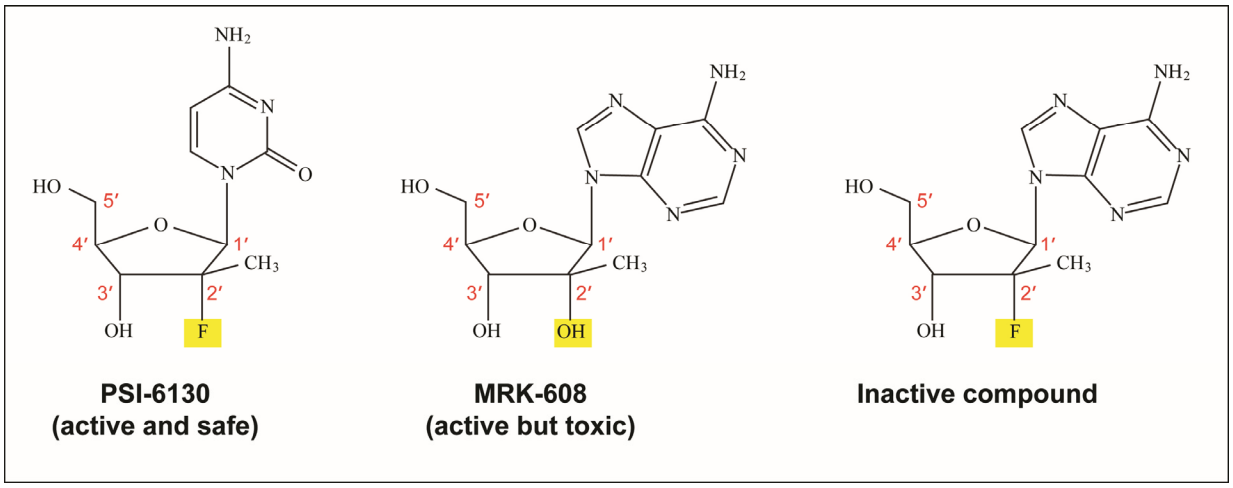
A. Merck's Claims Are Invalid For Lack Of Enablement Because The Specification Fails To Disclose A Practical Utility For The Claimed Compounds.

Section 112 separately imposes an enablement requirement. *See Ariad*, 598 F.3d at 1340. Whether a claim satisfies that requirement is a question of law based on underlying factual findings. *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012). This Court reviews an application of the enablement requirement "without deference" and the "factual underpinnings of enablement for substantial evidence." *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012) (quotation marks omitted).

Merck cannot satisfy the enablement requirement unless the original specification "disclosed as a matter of fact a practical utility" for the claimed sub-genuses. *In re Ziegler,* 992 F.2d 1197, 1200 (Fed. Cir. 1993). That disclosure requires more than "mere plausibility." *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325 (Fed. Cir. 2005); *see In re Fisher*, 421 F.3d 1365, 1373 (Fed. Cir. 2005). Rather, if a person skilled in the art would initially have "reason to doubt the objective truth" of a claim's asserted utility, the specification must provide "substantiating evidence" sufficient to quell that doubt. *Rasmusson*, 413 F.3d at 1323. Thus, "where there is no indication that one skilled in the art would accept without question statements as to the effects of the claimed drug products and no evidence has been presented to

demonstrate that the claimed products do have those effects," the patentee has failed to disclose a practical utility and the patent is invalid for lack of enablement. *Id.* (internal punctuation omitted). Moreover, a "complete absence of data supporting the statements which set forth the desired results of the claimed invention" supports finding a lack of practical utility. *Id.*; *see also In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1327 (Fed. Cir. 2009).

The evidence at trial demonstrated that a person of skill in the art would not have "accept[ed] without question" an assertion that the claimed sub-genuses were useful for treating HCV. In 2002, the study of nucleosides to target HCV was a new and highly unpredictable field. *See, e.g.*, Appx20056 (565:10-568:25); Appx20059-20060 (579:20-581:1) (Seeger); Appx20206-20208 (791:20-802:9) (Secrist). By way of illustration, compare these three compounds:



The compound on the right is useless against HCV. Make just one change—swap OH for F at 2'-down—and you get Merck's active but toxic compound, MK-608.

Make a different change—swap the pyrimidine base for purine—and you get Pharmasset's active and safe compound, PSI-6130. Appx20043-20044 (Otto); Appx24106-24108; Appx20069 (Seeger). A single atom makes all the difference.

Gilead's expert, Dr. Seeger, explained that, in light of the field's "unpredictability," a person of skill would not have believed the specification's bare assertion that the *millions* of claimed compounds were "useful" in HCV treatment without "data that support[ed] th[e] statement." Appx20059-20060 (580:11-581:1); *see also* Appx20210 (807:10-18) (Secrist). And Merck's own witnesses conceded that "[y]ou would need to test the compounds … in order to determine if they had … anti-HCV activity." Appx20495 (1381:24-1382:8) (Wentland); *see also* Appx20491 (Wentland); Appx32273-32277 (Carroll). In short, unrebutted expert testimony showed that there was a clear reason to doubt the purported utility of the claimed sub-genuses.

Under *Rasmusson*, the specification was required to provide "substantiating evidence" to quell that doubt. But the specification contained no data whatsoever for the claimed compounds. Instead, it offered only a vague allegation that a few unidentified "representative compounds" showed some activity against HCV. Appx217-218; *see also* A20131 (671:7-20) (Stella); Appx20328 (Olsen). As Merck conceded, however, ***none*** of those compounds fell within the claimed sub-genuses. Appx19582. The assay results were thus too far afield to reassure a person of ordinary skill in the art that the *sub-genuses* were useful against HCV. This Court has

long recognized that "[i]n cases involving unpredictable factors, such as most chemical and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). That rule decides this case. In an unpredictable field where a single atom can mean the difference between activity and uselessness, information about undisclosed compounds outside the sub-genuses was plainly insufficient to establish the utility of the claimed compounds. *See* Appx20055 (561:6-23); Appx20058-20059; Appx20060 (581:5-7) (Seeger).

Merck also sought to bolster its utility arguments by citing additional data about the sub-genuses that became available ***after*** the specification was filed, including sofosbuvir's test results. *See* Appx20481 (1324:10-23). But subsequently obtained data cannot buttress the practical utility of the claims because utility is assessed as of the filing date. *See In re '318 Patent Litig.*, 583 F.3d at 1323, 1325 n.8. And in any event, Merck's reliance on Gilead's work shows precisely why Merck's claims lack enablement: Merck made exceedingly broad "guesses" about billions of compounds in 2002, and now seeks to "be rewarded the spoils instead of the party who demonstrated that [specific compounds] actually worked." *Rasmusson*, 413 F.3d at 1325. Section 112 bars that type of recovery.

Ultimately, Merck again distorted the controlling legal standard in a bid to salvage its claims. It first sought judgment as a matter of law merely because the utility of the sub-genuses was not "implausible." Appx20512 (1449:23-1450:15).

Merck then urged the jury not to require substantiating evidence, arguing that "the Instructions don't say anything about data ... it doesn't say you have to prove anything. It says you have to disclose it, which we did." Appx20670-20671 (1700:23-1702:10). As this Court's precedent makes clear, however, "[m]ere plausibility" is not sufficient; a patent ***must*** provide "substantiating evidence" where, as here, a person skilled in the art would have "reason to doubt the objective truth" of a patent's assertions. *Rasmusson*, 413 F.3d at 1323. Merck's patents fail, as a matter of law, to meet that standard.

B. Merck's Claims Are Invalid For Lack Of Enablement Because They Require Undue Experimentation.

For similar reasons, the claims of the '499 patent and claims 1-3, 5, and 7 of the '712 patent also lack enablement because their full scope cannot be practiced without undue experimentation. *See Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013). This Court evaluates whether excessive experimentation is required by evaluating several factors, including the quantity of experimentation needed, the amount of guidance given, the presence or absence of working examples, the unpredictability of the field, and the breadth of the claims. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Those factors cut squarely against Merck's claims. *See* Appx20205-20209 (Secrist); Appx20130-20134 (Stella).

To begin with, although the claims are dramatically narrower than any formula in the specification, they still encompass millions of compounds and thus require a

tremendous amount of experimentation. Appx20129-20130 (661:17-665:7) (Stella); Appx20150 (747:18-25) (Secrist); Appx20205-20209 (789:17-803:20) (Secrist); Appx20059 (Seeger); *cf. Wyeth*, 720 F.3d at 1385 (claims that required testing "tens of thousands of candidates" were not enabled). The specification offers no guidance about where to begin that process—it fails to provide even one working example of a claimed compound, and it does not indicate that any particular substituent is preferred. Appx20129-20130 (664:21-667:14 (Stella); Appx20208-20209 (803:5-20) (Secrist); Appx20056 (565:13-566:7) (Seeger); *cf. Wyeth*, 720 F.3d at 1386 (claims were not enabled where specification offered only one working example and no further "guidance or predictions about particular substitutions" that were preferred); *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940-41 (Fed. Cir. 2010). Moreover, as even Merck's witnesses acknowledged, nucleoside activity was extremely unpredictable. Appx32283 (85:6-10, 104:16-19, 22) (Bennett); Appx32273 (123:18-25) (Carroll); Appx19913 (251:2-11) (Sofia); Appx20207 (796:8-797:20) (Secrist); Appx20044 (Otto); *see Wyeth*, 720 F.3d at 1386 (claims were not enabled in part because they required testing in an "unpredictable" area); *In re Vaeck*, 947 F.2d 488, 495-96 (Fed. Cir. 1991).

In sum, Merck's specification "disclose[d] only a starting point for further iterative research in an unpredictable and poorly understood field." *Wyeth*, 720 F.3d at 1386; *see ALZA*, 603 F.3d at 941. Even Merck's expert recognized as much. *See* Appx20480 (1319:23-25) (Wentland) (the specification "allow[ed] the inventors to

start their path toward trying to understand how these compounds work as inhibitors of NS5B and as inhibitors of viral replication"). The specification thus failed, as a matter of law, to enable Merck's claims.

CONCLUSION

For the reasons above, the Court should affirm the unclean hands judgment. If it does not, the Court should reverse the denial of JMOL on written description and enablement. At a minimum, this Court should reject Merck's request to reinstate the jury verdict. Gilead sought several other remedies below for Merck's misconduct, which the district court did not reach. Appx21969-21971. So if the court sets aside the unclean hands judgment and does not enter judgment of invalidity, it should remand for further consideration of those issues.

Dated: March 20, 2017

Respectfully submitted,

/s/ Jonathan E. Singer

Juanita R. Brooks
Jonathan E. Singer
Craig E. Countryman
Fish & Richardson P.C.
12390 El Camino Real
San Diego, CA 92130
(858) 678-5070
brooks@fr.com; singer@fr.com;
countryman@fr.com

Deanna J. Reichel
Fish & Richardson P.C.
3200 RBC Plaza
60 South Sixth Street
Minneapolis, MN 55402
(612) 335-5070
reichel@fr.com

Elizabeth M. Flanagan
Robert M. Oakes
Fish & Richardson P.C.
222 Delaware Avenue
17th Floor, P.O. Box 1114
Wilmington, DE 19801
(302) 652-5070
flanagan@fr.com; oakes@fr.com

E. Joshua Rosenkranz
Rachel Wainer Apter
Edmund Hirschfeld
Orrick, Herrington & Sutcliffe LLP
51 West 52nd Street
New York, NY 10019-6142
(212) 506-5000
jrosenkranz@orrick.com

Attorneys for Cross-Appellant Gilead Sciences, Inc.

CERTIFICATE OF SERVICE AND FILING

I certify that I electronically filed the foregoing document using the Court's CM/ECF filing system on March 20, 2017. All counsel of record were served via CM/ECF on March 20, 2017.

/s/ Jonathan E. Singer
Jonathan E. Singer

CERTIFICATE OF COMPLIANCE

The undersigned attorney certifies that Gilead's Principal and Response Brief complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B). The relevant portions of the brief, including all footnotes, contain 16,457 words, as determined by Microsoft Word.

Dated: March 20, 2017

/s/ Jonathan E. Singer

Jonathan E. Singer
Fish & Richardson P.C.
12390 El Camino Real
San Diego, CA 92130
(858) 678-5070
singer@fr.com